"(i) is a business that meets the applicable industry-based small business size standard established by the Administrator of the Small Business Administration under section 3 of the Small Business Act; and

"(ii) has had an average of less than $500,000 in annual domestic cosmetic sales over the previous 3 years.

"(B) CONTENTS.—A responsible person described in subparagraph (A) shall include in each cosmetic ingredient statement under this section, at a minimum, a list of ingredients in the cosmetic product and the applicable cosmetic category for the cosmetic product.

"(d) INCOMPLETE OR INACCURATE COSMETIC INGREDIENT STATEMENT.—

"(1) IN GENERAL.—Not earlier than 10 days after providing notice under paragraph (2), the Food and Drug Administration may nullify a cosmetic ingredient statement filed under this section if the Food and Drug Administration has reasonable grounds to believe that the cosmetic ingredient statement was not completed or updated in accordance

with this section or otherwise contains false, incomplete, or inaccurate information.

"(2) NOTICE OF NULLIFICATION.—A nullification under paragraph (1) shall be preceded by notice to the responsible person of the intent to cancel the cosmetic ingredient statement and the basis for such cancellation.

"(3) TIMELY UPDATE OR CORRECTION.—If the cosmetic ingredient statement is appropriately updated or corrected not later than 7 days after notice is provided under paragraph (1), the Food and Drug Administration shall not nullify such cosmetic ingredient statement.

"(e) ADDITIONAL REQUIREMENTS.—

"(1) SAFETY REQUIREMENTS.—In filing each cosmetic ingredient statement cosmetic product, the responsible person shall include an attestation that the safety of the product, including the individual ingredients of such product and the product as a whole, has been substantiated in accordance with section 609. In the case of a cosmetic ingredient statement that includes a range of possible amounts (as described in subsection (c)(2)(E)), the responsible person shall include an attestation that the

safety of the full range in the finished product has been substantiated, in accordance with section 609.

"(2) ABBREVIATED FILING.—The Food and Drug Administration shall provide for an abbreviated renewal process for any such filing with respect to which there has been no change since the responsible person submitted the previous filing.

"(3) CHANGES TO INFORMATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the responsible person shall notify the Food and Drug Administration within 60 days of any change to the information required to be in a cosmetic ingredient statement, including discontinuation of the manufacture of a cosmetic product, except that notification under this paragraph is not required for a change in—

"(i) the amount of an existing ingredient if it is within the range previously reported under subsection (c)(2)(E); or

"(ii) the addition or subtraction of a fragrance, flavor, or color, or such other interchangeable ingredients specified by the Food and Drug Administration in regulations or guidance, previously reported

as a potential ingredient under subsection (c)(2)(E), if, in the case of an addition of such an ingredient, the amount is within the range previously reported.

"(B) SMALL BUSINESS.—The Food and Drug Administration shall allow a responsible person that is a business that meets the applicable industry-based small business size standard established by the Administrator of the Small Business Administration under section 3 of the Small Business Act to have a period longer than 60 days, but not longer than the next annual registration deadline under section 605(a)(1), to submit any change to the information required to be in a cosmetic ingredient statement as described in subparagraph (A).

"(f) COSMETIC PRODUCTS LIST.—At the time of the initial submission of any cosmetic ingredient statement under this section, the Food and Drug Administration shall assign a unique cosmetic product listing number to the cosmetic ingredient statement. Based on such cosmetic ingredient statements, the Food and Drug Administration shall compile and maintain a list of cosmetic products distributed in the United States, including the ingredients of each such product, and shall make available such list

to any State, upon request. Information disclosed to a State that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State.

"SEC. 607. SUSPENSION OF REGISTRATION OR COSMETIC INGREDIENT STATEMENT.

"(a) SUSPENSION OF REGISTRATION OF A FACILITY.—If the Food and Drug Administration determines that a cosmetic formulation or cosmetic product manufactured, processed, packed, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans, and there is reason to believe that other formulations or products manufactured, processed, packed, or held by the facility may be similarly affected because of a failure affecting multiple products in that facility, the Food and Drug Administration may suspend the registration of a facility.

"(b) SUSPENSION OF COSMETIC INGREDIENT STATEMENT.—If the Food and Drug Administration determines that a cosmetic product manufactured in a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans, the Food and Drug Administration may suspend the cosmetic ingredient statement of that product.

"(c) NOTICE OF SUSPENSION.—Before suspending a facility registration or a cosmetic ingredient statement under this section, the Food and Drug Administration shall provide—

"(1) notice to the facility registrant of the cosmetic product or formulation or other responsible person, as appropriate, of the intent to suspend the facility registration or the cosmetic ingredient statement, which shall specify the basis of the determination by the Food and Drug Administration that the facility or the cosmetic ingredient should be suspended and recommendations for specific actions to avoid suspension; and

"(2) an opportunity, within 2 business days of the notice provided under paragraph (1), for the responsible person to address the reasons for possible suspension of the facility registration or cosmetic ingredient statement.

"(d) REINSTATEMENT.—Upon a determination by the Food and Drug Administration that adequate grounds do not exist to continue the suspension actions, the Food and Drug Administration shall promptly vacate the suspension and reinstate the registration of the facility or the cosmetic ingredient statement.

"(e) EFFECT OF SUSPENSION.—

"(1) REGISTRATION.—If the registration of a facility is suspended under this section, no person shall import or export cosmetics or otherwise distribute cosmetics from such facility.

"(2) COSMETIC INGREDIENT STATEMENT.—If the cosmetic ingredient statement for a cosmetic product is suspended under this section, no person shall import or export such cosmetic product or otherwise distribute in the United States such cosmetic product that is the subject of such statement.

"(f) NO DELEGATION.—The authority conferred by this section to issue an order to suspend a registration or vacate an order of suspension shall not be delegated to any officer or employee other than the Commissioner.".

SEC. 102. REVIEW OF INGREDIENTS AND NON-FUNCTIONAL CONSTITUENTS; SAFETY OF FINISHED PRODUCTS.

(a) AMENDMENTS.—Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 101, is further amended by adding at the end the following:

"SEC. 608. REVIEW OF INGREDIENTS AND NON-FUNCTIONAL CONSTITUENTS.

"(a) INGREDIENTS AND NON-FUNCTIONAL CONSTITUENTS SUBJECT TO REVIEW.—

"(1) IN GENERAL.—Beginning in fiscal year 2016, the Food and Drug Administration shall review the safety of the cosmetic ingredients and non-functional constituents under paragraph (3), as modified under subsection (c), if applicable, and issue an order under subsection (d) with respect to the use of each such ingredient and presence of each such non-functional constituent.

"(2) PUBLIC NOTICE AND COMMENT.—At the initiation of the review of each cosmetic ingredient or non-functional constituent, the Food and Drug Administration shall open a docket for the submission of public comment and additional data relevant to the safety of the ingredient or non-functional constituent. The Food and Drug Administration shall provide 60 days for public comment.

"(3) COSMETIC INGREDIENTS.—

"(A) INGREDIENTS TO BE CONSIDERED IN FIRST YEAR.—During fiscal year 2016, the Food and Drug Administration shall initiate the review for safety of the following cosmetic ingredients:

"(i) Diazolidinyl urea.

"(ii) Lead acetate.

"(iii) Methylene glycol/methanediol/formaldehyde.

"(iv) Propyl paraben.

"(v) Quaternium-15.

"(B) INGREDIENTS TO BE CONSIDERED IN SUBSEQUENT YEARS.—

"(i) IN GENERAL.—Beginning in fiscal year 2017, the Food and Drug Administration shall annually select and complete review of at least 5 cosmetic ingredients or non-functional constituents that were not reviewed in the prior 3 years from a list determined in consultation with industry and consumer groups for review of safety. The Food and Drug Administration may modify such list under subsection (c).

"(ii) CONSIDERATIONS.—The determination of which ingredients or functional ingredients will be reviewed in a given year shall be publicized in annual reports to Congress and the public, in accordance with section 618, and subject to consultation as provided for in clause (iii). The review of any cosmetic ingredient or non-functional constituent shall commence with

a public announcement by the Food and Drug Administration and the opening of a docket as required under paragraph (2).

"(iii) CONSULTATION.—The Food and Drug Administration shall establish a Cosmetics Safety Advisory Committee, which shall include equal numbers of individuals from the cosmetics industry and consumer groups, and other individuals, as the Food and Drug Administration determines appropriate, including medical practitioners. Such advisory committee shall advise the Food and Drug Administration on cosmetic ingredients and non-functional constituents to be considered for review, summarize public comments received pursuant to paragraph (4), and recommend 5 cosmetic ingredients or non-functional constituents to be reviewed for safety each year, as described in clause (i). The Food and Drug Administration may consult with the Cosmetics Safety Advisory Committee on other matters pertaining to cosmetic safety.

"(4) COMMENT PERIOD.—As part of the annual reporting to Congress and the public under section 618, the Food and Drug Administration shall solicit public comment on which cosmetic ingredients or non-functional constituents on the list are of greatest interest to be reviewed next for early review and which additional cosmetic ingredients or non-functional constituents should be added to the list. The public may submit comments to the Food and Drug Administration at any time during the year regarding which cosmetic ingredients or non-functional constituents of interest that the Food and Drug Administration may consider during that year or subsequent years.

"(b) LIST.—The Food and Drug Administration shall maintain a list, posted on the Internet website of the Food and Drug Administration, of the cosmetic ingredients and non-functional constituents for which final orders have been issued under subsection (d)(3), the finding made for each such ingredient or non-functional constituent under subsection (d)(4), as modified by any order under subsection (f), and, if applicable, compliance dates that are the subject of a final order under subsection (e).

"(c) INITIATIVE OF THE FDA.—The Food and Drug Administration may at any time, after consultation with

the Cosmetics Safety Advisory Committee, propose the issuance of an order on the safety of a cosmetic ingredient or non-functional constituent that was not previously listed in subsection (a) or under section 618(a)(3).

"(d) DETERMINATION ON SAFETY.—

"(1) INITIAL PROPOSED ADMINISTRATIVE ORDER.—Following consideration of data and comments to the public docket and any other information before the Food and Drug Administration, the Food and Drug Administration shall determine whether there is adequate evidence to make an initial finding on the safety of the ingredient or non-functional constituent. If the Food and Drug Administration determines that there is adequate evidence, the Food and Drug Administration shall issue a proposed administrative order and shall post such order on the Internet website of the Food and Drug Administration, notwithstanding subchapter II of chapter 5 of title 5, United States Code.

"(2) PUBLIC COMMENT.—Upon publication of the proposed administrative order described in paragraph (1), the Food and Drug Administration shall open a docket for the submission of public comment. The Food and Drug Administration shall provide 30

days for public comment following publication of the proposed administrative order.

"(3) FINAL ADMINISTRATIVE ORDER.—Following the public comment period described in paragraph (2) and consideration of comments to the public docket and any other information before the Food and Drug Administration, the Food and Drug Administration shall determine whether there is adequate evidence to make a final finding on the safety of the ingredient or non-functional constituent. If the Food and Drug Administration determines that there is adequate evidence, the Food and Drug Administration shall issue a final administrative order and shall post such order on the Internet website of the Food and Drug Administration, notwithstanding subchapter II of chapter 5 of title 5, United States Code.

"(4) DETERMINATIONS.—In the proposed administrative order or the final administrative order, as applicable, the Food and Drug Administration shall make a determination that the ingredient or non-functional constituent is—

"(A) safe in cosmetic products under specified conditions of use or tolerances;

"(B) safe in cosmetic products without the need for specified conditions of use or tolerances; or

"(C) not safe in cosmetic products.

"(5) CONDITIONS OF USE AND TOLERANCES.—An order under paragraph (4)(A) shall include such conditions on the use of an ingredient or such tolerances on the presence of a non-functional constituent as are necessary for the safety of cosmetic products containing such ingredient or non-functional constituent, including—

"(A) limits on the amount or concentration of the ingredient or non-functional constituent that may be present in a cosmetic product, including limits in products intended for children and other vulnerable populations, and limits on use near the eye or mucosal membranes;

"(B) warnings that are necessary or appropriate under section 614, including warnings related to use by children, pregnant women, populations with high exposure to the ingredient (such as workers who are exposed through production practices or handling of final products), or other vulnerable populations, to help ensure

safe use of cosmetic products containing the ingredient or non-functional constituent; and

"(C) such other conditions as are necessary for the safety of cosmetic products containing such ingredient or non-functional constituent.

"(6) PUBLIC NOTICE.—A final order under this subsection shall set forth the determination of the Food and Drug Administration on safety, any conditions of use or tolerances under subparagraph (A) or (B) of paragraph (4) and a summary of the valid scientific evidence supporting the finding. The order shall be effective upon its publication on the Internet website of the Food and Drug Administration and shall be considered final agency action.

"(e) ORDER.—If the Food and Drug Administration issues a final administrative order under subparagraph (A) or (C) of subsection (d)(4), the Food and Drug Administration shall, at the same time as publication of the notice under subsection (d)(6), publish a proposed order identifying dates by which use of the ingredient or non-functional constituent in cosmetic products shall comply with the final administrative order, and provide 60 days for public comment, including comment on whether compliance is feasible within the proposed dates. After consid-

ering comments on the proposed order, the Food and Drug Administration shall publish in the Federal Register a final order.

"(f) MODIFICATION OF AN ORDER.—An order issued under subsection (d) or (e) may be modified or revoked by the Food and Drug Administration on the initiative of the Food and Drug Administration or in response to a petition.

"(g) INADEQUATE EVIDENCE.—

"(1) NOTICE; EXTENSION.—If the Food and Drug Administration determines that the available data and information are not adequate to make a proposed or final determination regarding safety under subsection (d)(4), with respect to a cosmetic ingredient or non-functional constituent, the Food and Drug Administration shall—

"(A) publish such finding on the Internet website of the Food and Drug Administration not later than 90 days after the close of the relevant comment period for the ingredient or non-functional constituent under subsection (a)(2), in the case of a proposed order, or subsection (d)(2), in the case of a final order; and

"(B)(i) include a notice providing interested persons an additional 30 days from the

notice date to provide additional data and information; and

"(ii) if, after the 30-day period under clause (i), the Food and Drug Administration determines that additional safety substantiation with respect to such ingredient or non-functional constituent is necessary to make a safety determination, include a notice specifying an additional time period, not to exceed 18 months from the notice date, and plan to obtain such data and information.

"(2) DETERMINATION; ORDER.—

"(A) INADEQUATE DATA AND INFORMATION.—If the Food and Drug Administration determines, after considering any additional data and information submitted under paragraph (1)(B), that the available data and information still are not adequate to make a determination regarding safety under subsection (d)(4), the Food and Drug Administration shall, within 90 days of the close of the additional time period provided under paragraph (1)(B), issue a proposed order or a final administrative order—

"(i) making a determination that the ingredient or non-functional constituent has not been shown to be safe in cosmetic products; and

"(ii) explaining why the available data and information are not adequate to assess the safety of the ingredient or non-functional constituent.

"(B) ADEQUATE DATA AND INFORMATION.—If the Food and Drug Administration determines, after considering any additional data and information submitted under paragraph (1)(B), that the available data and information are adequate to make a determination regarding safety under subsection (d)(4), the Food and Drug Administration shall, within 180 days of the close of the comment period, issue a proposed order, followed by a final order, on such cosmetic ingredient or non-functional constituent, in accordance with such subsection.

"(h) SAFETY ASSESSMENT.—

"(1) IN GENERAL.—In assessing the safety of an ingredient or non-functional constituent, the Food and Drug Administration shall consider wheth-

er there is adequate evidence to support a reasonable certainty among competent scientists that the ingredient is not harmful under the recommended or suggested conditions of use or customary or usual use, or that a non-functional constituent is not harmful under the recommended or suggested tolerance levels or the level at which it is customarily or usually present. The Food and Drug Administration may not consider an ingredient or non-functional constituent harmful solely because it can cause minor adverse health reactions, such as minor transient allergic reactions or minor transient skin irritations, in some users.

"(2) FACTORS.—In assessing the safety of an ingredient or non-functional constituent, the Food and Drug Administration shall consider, among other relevant factors, the following:

"(A) The probable human exposure to the ingredient or non-functional constituent from expected use in cosmetics.

"(B) The probable cumulative and aggregate effect in humans of relevant exposure to the ingredient or non-functional constituent or to any chemically or pharmacologically related substances from use in cosmetics or other prod-

ucts with similar routes of exposure under recommended or suggested conditions of use or their customary use, to the extent adequate data is available for analysis. In appropriate cases, the Food and Drug Administration may consider available information on the total exposure to an ingredient or non-functional constituent from all sources.

"(C) Whether warnings or recommendations in a product label, as part of any conditions of use or tolerances imposed by the Food and Drug Administration, would be necessary and appropriate to help ensure the safety of the ingredient or non-functional constituent.

"(3) DATA AND INFORMATION.—

"(A) REQUIRED INFORMATION.—A determination that an ingredient or non-functional constituent is safe in cosmetics shall be based upon adequate evidence submitted or otherwise known to the Food and Drug Administration, which shall include full reports of all available studies, published or unpublished, that are adequately designed to show whether the ingredient or non-functional constituent is safe. Such studies may include in vitro and in silico studies

and epidemiological studies, biomonitoring studies, and studies focused on various points during the lifespan of the subject, that use scientifically valid methodology.

"(B) ADDITIONAL RELEVANT INFORMATION.—The Food and Drug Administration shall consider any other relevant information related to the safety of the ingredient or non-functional constituent, including—

"(i) adverse event reports;

"(ii) findings and information from State, Federal, national, and international entities and other bodies composed of scientific and medical experts;

"(iii) if the ingredient or non-functional constituent is lawfully used or present in other products regulated by the Food and Drug Administration, the scientific basis for such use; and

"(iv) experience with the ingredient or non-functional constituent in products that are distributed in the United States or in other countries, if such experience is well-documented and has resulted in substantial

human exposure to the ingredient or non-functional constituent over time.".

"SEC. 609. SAFETY OF FINISHED COSMETIC PRODUCTS.

"(a) DETERMINATION.—

"(1) IN GENERAL.—Each responsible person for a finished cosmetic product shall, before first distributing the product for sale, make a written determination that the product is safe under the conditions of use recommended in the labeling of the product. Such determination shall be based on adequate evidence that each ingredient in the finished product is safe for the use recommended or suggested in the labeling of the product and that the finished product is safe.

"(2) NEW INFORMATION.—If new information relevant to the determination becomes available, the responsible person shall promptly update the determination to address that information.

"(3) SAFETY WITH RESPECT TO RANGES OF POSSIBLE AMOUNTS.—In the case of a cosmetic product for which there is a range of possible amounts of cosmetic ingredients included in the cosmetic ingredient statement, as described in section 606(c)(2)(E), the safety determination under para-

graph (1) shall include substantiation of the safety of the full range in the finished product.

"(b) PRESUMPTION OF ADEQUATE EVIDENCE.—

"(1) IN GENERAL.—Except as provided in subsection (c), a determination made under subsection (a) shall be presumed to be based on adequate evidence if it is supported by—

"(A) with respect to each ingredient in the finished product—

"(i) references to an official statement by one or more expert medical or scientific bodies that the ingredient is safe under the conditions of use recommended or suggested in the product's labeling; or

"(ii) appropriate safety testing of the ingredient; and

"(B) appropriate safety substantiation of the finished product beyond the safety substantiation of individual ingredients and consideration of the combination of ingredients.

"(2) STATEMENT OF AN EXPERT MEDICAL OR SCIENTIFIC BODY.—For purposes of this section, a statement of an expert medical or scientific body is an official statement of that body, if—

"(A) the medical or scientific body is a Federal, State, national, or international entity with recognized expertise in chemical or cosmetic safety, or other similarly recognized body composed of scientific and medical experts;

"(B) the statement is based upon adequate data to support the finding of safety, and such data are available to the Food and Drug Administration; and

"(C) the statement is published and endorsed by the medical or scientific body and is not a statement of an employee of such body made in the individual capacity of the employee.

"(c) REBUTTAL OF PRESUMPTION.—Notwithstanding subsection (b), a determination under subsection (a) will not be presumed to be based on adequate evidence if—

"(1) the Food and Drug Administration issues an order under section 608 that an ingredient or non-functional constituent in the finished product is not safe under the product's conditions of use or customary or usual use; or

"(2) the Food and Drug Administration has provided the manufacturer with notice that—

"(A) the manufacturer has not met the criteria under subsection (b); or

"(B) the Food and Drug Administration has information that raises significant questions about the safety of the product or any of its ingredients.

"(d) TIMELY UPDATE.—Upon notice of inadequate evidence under subsection (c), the responsible person shall have 10 days to submit additional evidence to the Food and Drug Administration regarding the safety of an ingredient, non-functional constituent, or the entire cosmetic product, and the Food and Drug Administration shall have 30 days from the date of receipt of such additional evidence to provide the responsible person with notice that the criteria under subsection (b) have been met or not met.

"(e) RECORDS MAINTENANCE.—The responsible person shall maintain records documenting the determination required under this section and the information on which it is based until 5 years after the finished product is no longer marketed.

"(f) SUBMISSION OF RECORDS.—

"(1) IN GENERAL.—The records required under subsection (e) shall, upon the written request of the Food and Drug Administration to the responsible person, be provided to the Food and Drug Adminis-

tration within a reasonable timeframe not to exceed 60 days, in either electronic or paper form.

"(2) CRITERIA.—The Food and Drug Administration may require records under paragraph (1) if—

"(A) the Food and Drug Administration has a reasonable belief, described in written notice, that—

"(i) the finished product may be harmful based on adverse event reports or other scientific information;

"(ii) scientific information raises credible and relevant questions about the safety of the product or any of its ingredients;

"(iii) the responsible person has not made the determination required under subsection (a), or such determination is not supported by adequate evidence; or

"(iv) one or more of the criteria to establish a presumption of adequate evidence of safety in subsection (b) has not been satisfied;

"(B) the Food and Drug Administration, an expert regulatory body, or an expert body composed of scientific and medical experts finds

an ingredient in the product to be unsafe under the conditions of use of the product; or

"(C) the Food and Drug Administration concludes that submission of the records will serve the public health or otherwise enable the Food and Drug Administration to fulfill the cosmetic safety purposes of this section.

"(g) GUIDANCE AND REGULATIONS.—

"(1) IN GENERAL.—The Food and Drug Administration shall issue guidance describing the evidence necessary to support a determination under subsection (a), and may, by regulation, establish exemptions to the requirements of this section, if the Food and Drug Administration determines that such exemptions are supported by adequate evidence and would have no adverse effect on public health.

"(2) SMALL BUSINESSES.—The Food and Drug Administration shall, after consultation with the Small Business Administration and small businesses that manufacture cosmetics, provide additional guidance for small businesses on compliance with the requirements of this section. Such guidance shall include specific examples of options for compliance that do not place an undue burden on small businesses.".

(b) EFFECTIVE DATE.—Section 609 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall take effect 180 days after the date of enactment of this Act.

SEC. 103. GOOD MANUFACTURING PRACTICES FOR COSMETICS.

(a) IN GENERAL.—Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 102, is further amended by adding at the end the following:

"SEC. 610. GOOD MANUFACTURING PRACTICES FOR COSMETICS.

"(a) IN GENERAL.—The Food and Drug Administration shall review national and international standards for cosmetic good manufacturing practices that are in existence on the date of enactment of the Personal Care Products Safety Act and shall develop and implement, through regulations, United States standards consistent, to the extent the Food and Drug Administration determines practicable and appropriate, with such national and international standards for cosmetic good manufacturing practices to ensure that requirements of this chapter with respect to the manufacture of cosmetic products are in harmony.

"(b) TIMEFRAME.—The Food and Drug Administration shall publish a proposed rule described in subsection (a) not later than 18 months after the date of enactment of the Personal Care Products Safety Act and shall publish a final such rule not later than 3 years after such date of enactment.".

(b) EFFECTIVE DATE FOR COSMETIC MANUFACTURERS.—

(1) LARGE BUSINESSES.—For businesses of a size greater than the Small Business Administration's standard for a small business, section 610 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) shall take effect beginning 180 days after the date on which the Food and Drug Administration makes effective cosmetic good manufacturing practices.

(2) SMALL BUSINESSES.—For businesses of a size that meets the Small Business Administration's standard for a small business, section 610 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) shall take effect beginning 2 years after the date the Food and Drug Administration makes effective cosmetic good manufacturing practices.

(c) ENFORCEMENT.—Section 601 of Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361) is amended by adding at the end the following:

"(f) If the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to current good manufacturing practice, as prescribed by the Food and Drug Administration.".

SEC. 104. ADVERSE EVENT REPORTS.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 103(a), is further amended by adding at the end the following:

"SEC. 611. ADVERSE EVENT REPORTING FOR COSMETICS.

"(a) IN GENERAL.—With respect to any cosmetic product distributed in the United States, the responsible person shall submit to the Food and Drug Administration a report of any serious adverse event associated with such cosmetic product, when used in the United States, accompanied by a copy of the label on or with the retail packaging of the cosmetic, any new medical information, related to a submitted serious adverse event report that is received by the responsible person, and an annual report for all adverse events received by the responsible person.

"(b) DEFINITIONS.—In this section:

"(1) An 'adverse event' for a cosmetic product is a health-related event associated with the use of this product that is adverse.

"(2) A 'serious adverse event' for a cosmetic product is an adverse event that—

"(A) results in—

"(i) death;

"(ii) a life-threatening experience;

"(iii) inpatient hospitalization;

"(iv) a persistent or significant disability or incapacity;

"(v) congenital anomaly or birth defect; or

"(vi) significant disfigurement, including serious and persistent rashes and infections; or

"(B) requires, based on appropriate medical judgment, a medical or surgical intervention to prevent an outcome described in subparagraph (A).

"(c) SUBMISSION OF REPORTS.—

"(1) SERIOUS ADVERSE EVENT REPORTS.—Except as provided in paragraph (2), the responsible person shall submit a serious adverse event report to the Food and Drug Administration not later than 15

business days after information concerning the adverse event is received. If a serious adverse event report for a cosmetic with drug properties is filed using Form FDA 3500A (or any successor form developed for such purpose) or its electronic equivalent for over-the-counter drugs, the responsible person shall not have to submit a duplicative serious adverse event report under this section.

"(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Food and Drug Administration any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, and shall submit such information not later than 15 business days after the new information is received by the responsible person.

"(3) ANNUAL REPORT.—

"(A) IN GENERAL.—Not later than March 1 of each year, the responsible person shall submit an electronic report for the prior calendar year for each cosmetic product marketed during that year.

"(B) CONTENTS.—Each report under this paragraph shall contain a summary of all adverse events received during the reporting pe-

riod, a complete list of individual reports, and an estimate of the total number of product units estimated to have been distributed to consumers during such period. The report shall not include consumer complaints that are solely regarding efficacy and do not contain any information about an adverse event. The Food and Drug Administration shall further specify the contents of the annual electronic report by regulation or guidance.

"(4) EXEMPTION.—The Food and Drug Administration may establish by regulation an exemption to any of the requirements under this subsection if the Food and Drug Administration determines that such exemption is supported by adequate evidence and would have no adverse effect on public health.

"(d) REQUIREMENTS.—

"(1) IN GENERAL.—Each serious adverse event report under this section shall be submitted to the Food and Drug Administration using an electronic system of the Food and Drug Administration. The Food and Drug Administration shall make such electronic system available not later than 1 year after

the date of enactment of the Personal Care Products Safety Act.

"(2) MODIFICATION.—The format of the reporting system may be modified by the Food and Drug Administration and the reports may include additional information. The Food and Drug Administration may, in guidance, further specify the format and contents of required reports.

"(3) SCOPE OF SERIOUS ADVERSE EVENT REPORT.—A serious adverse event report (including all information submitted in the initial report or added later) submitted to the Food and Drug Administration under subsection (a) includes—

"(A) a report under section 756 with respect to safety and related to a specific cosmetic product;

"(B) a record about an individual who suffered the serious adverse event under section 552a of title 5, United States Code;

"(C) a medical or similar file documenting the serious adverse event, the disclosure of which would constitute a violation of section 552(b)(6) of such title 5, and shall not be publicly disclosed unless all personally identifiable information is redacted; and

"(D) contact information for the individual reporting the serious adverse event.

"(4) RESPONSIBILITY TO GATHER INFORMATION.—After an individual initiates the reporting of a serious adverse event, the responsible person for the cosmetic product shall actively gather all of the information to complete and file the report with the Food and Drug Administration.

"(5) NO ADVERSE EVENTS TO REPORT.—The Food and Drug Administration shall provide an option as part of the electronic registration process for the responsible person to indicate if such responsible person had no adverse events to report over the previous year. With respect to a responsible person who received no adverse event reports for a year, the annual adverse event report requirement may be met by indicating no such events on the annual registration form.

"(e) LIMITATION WITH RESPECT TO ADVERSE EVENT REPORTS.—The submission of an adverse event report in compliance with subsection (a) shall not constitute an admission that the cosmetic involved caused or contributed to the adverse event.

"(f) CONTACT INFORMATION.—The label of a cosmetic shall bear the domestic telephone number or elec-

tronic contact information, and it is encouraged that the label include both the telephone number and electronic contact information, through which the responsible person may receive a report of an adverse event.

"(g) MAINTENANCE OF RECORDS.—The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

"(h) AVAILABILITY TO STATES.—The Food and Drug Administration shall make available records submitted under this section to any State, upon request. Information disclosed to a State that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State.

"(i) EFFECTIVE DATE OF REQUIREMENT WITH RESPECT TO SERIOUS ADVERSE EVENTS.—The requirement under this section to report serious adverse events shall become effective on the date that the Food and Drug Administration publicizes the availability of the electronic system described in subsection (d)(1).".

SEC. 105. RECORDS INSPECTION; MANDATORY RECALL AUTHORITY.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 104, is further amended by adding at the end the following:

"SEC. 612. INSPECTION OF COSMETIC RECORDS.

"(a) INSPECTION OF RECORDS.—Each manufacturer, processor, packer, or holder of a cosmetic shall, at the request of an officer or employee duly designated by the Food and Drug Administration, permit such officer or employee, upon presentation of appropriate credentials and written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy—

"(1) all records maintained under section 611 and in accordance with the rules promulgated by the Food and Drug Administration under section 610, as applicable; and

"(2) except as provided in subsection (b), all other records, if the Food and Drug Administration—

"(A) has a reasonable belief that the cosmetic—

"(i) is adulterated;

"(ii) has caused a reportable serious adverse event; or

"(iii) contains an ingredient that substantial new scientific information shows may be unsafe when present in a cosmetic; and

"(B) provides written notice of the basis for the Food and Drug Administration's reasonable belief described in subparagraph (A).

"(b) EXCLUSIONS.—No inspection authorized by this section shall extend to financial data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to this Act), research data (other than safety data) or sales data other than shipment data.

"(c) SCOPE.—The requirements under subsection (a) apply to records maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.

"(d) PROTECTION OF SENSITIVE INFORMATION.—The Food and Drug Administration shall take appropriate measures to ensure that there are effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Food and Drug Administration pursuant to this section. Information disclosed to a State that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be

treated as a trade secret and confidential information by the State.

"(e) LIMITATIONS.—This section shall not be construed—

"(1) to limit the authority of the Food and Drug Administration to inspect records or to require establishment and maintenance of records under any other provision of this Act; or

"(2) to have any legal effect on section 552 of title 5, United States Code, or section 1905 of title 18, United States Code.".

"SEC. 613. MANDATORY RECALL AUTHORITY.

"(a) VOLUNTARY PROCEDURES.—If the Food and Drug Administration determines that there is a reasonable probability that a cosmetic is adulterated under section 601 or misbranded under section 602 and the use of or exposure to such cosmetic is likely to cause serious adverse health consequences or death, the Food and Drug Administration shall provide the responsible person with an opportunity to voluntarily cease distribution and recall such article.

"(b) PREHEARING ORDER TO MANDATORILY CEASE DISTRIBUTION AND GIVE NOTICE.—

"(1) IN GENERAL.—If the responsible person refuses to or does not voluntarily cease distribution

or recall such cosmetic within the time and in the manner prescribed by the Food and Drug Administration, the Food and Drug Administration may order such person to—

"(A) immediately cease distribution of such cosmetic; and

"(B) as applicable, immediately notify all persons—

"(i) manufacturing, processing, packing, transporting, holding, receiving, distributing, or importing and selling such cosmetic; and

"(ii) to which such cosmetic has been distributed, transported, or sold,

to immediately cease distribution of such cosmetic.

"(2) REQUIRED ADDITIONAL INFORMATION.—

"(A) IN GENERAL.—If a cosmetic covered by a recall order issued under paragraph (1)(B) has been distributed to a warehouse-based third party logistics provider without providing such provider sufficient information to know or reasonably determine the precise identity of such cosmetic covered by a recall order that is in its possession, the notice provided by the respon-

sible person subject to the order issued under paragraph (1)(B) shall include such information as is necessary for the warehouse-based third party logistics provider to identify the cosmetic.

"(B) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

"(i) to exempt a warehouse-based third party logistics provider from the requirements of this chapter, including the requirements of this section and section 612; or

"(ii) to exempt a warehouse-based third party logistics provider from being the subject of a mandatory recall order.

"(3) DETERMINATION TO LIMIT AREAS AFFECTED.—If the Food and Drug Administration requires a responsible person to cease distribution under paragraph (1)(A) of a cosmetic, the Food and Drug Administration may limit the size of the geographic area and the markets affected by such cessation if such limitation would not compromise the public health.

"(c) HEARING ON ORDER.—The Food and Drug Administration shall provide the responsible party subject to an order under subsection (b) with an opportunity for an

informal hearing, to be held as soon as possible, but not later than 2 days after the issuance of the order, on the actions required by the order and on why the cosmetic that is the subject of the order should not be recalled.

"(d) POST-HEARING RECALL ORDER AND MODIFICATION OF ORDER.—

"(1) AMENDMENT OF ORDER.—If, after providing opportunity for an informal hearing under subsection (c), the Food and Drug Administration determines that removal of the cosmetic from commerce is necessary, the Food and Drug Administration shall, as appropriate—

"(A) amend the order to require recall of such cosmetic or other appropriate action;

"(B) specify a timetable in which the recall shall occur;

"(C) require periodic reports to the Food and Drug Administration describing the progress of the recall; and

"(D) provide notice to consumers to whom such cosmetic was, or may have been, distributed.

"(2) VACATING OF ORDER.—If, after such hearing, the Food and Drug Administration determines that adequate grounds do not exist to continue the

actions required by the order, or that such actions should be modified, the Food and Drug Administration shall vacate the order or modify the order.

"(e) COOPERATION AND CONSULTATION.—The Food and Drug Administration shall work with State and local public health officials in carrying out this section, as appropriate.

"(f) PUBLIC NOTIFICATION.—In conducting a recall under this section, the Food and Drug Administration shall—

"(1) ensure that a press release is published regarding the recall, and that alerts and public notices are issued, as appropriate, in order to provide notification—

"(A) of the recall to consumers and retailers to whom such cosmetic was, or may have been, distributed; and

"(B) that includes, at a minimum—

"(i) the name of the cosmetic subject to the recall;

"(ii) a description of the risk associated with such article; and

"(iii) to the extent practicable, information for consumers about similar cos-

metics that are not affected by the recall; and

"(2) ensure publication on the Internet website of the Food and Drug Administration an image of the cosmetic that is the subject of the press release described in paragraph (1), if available.

"(g) NO DELEGATION.—The authority conferred by this section to order a recall or vacate a recall order shall not be delegated to any officer or employee other than the Commissioner.

"(h) EFFECT.—Nothing in this section shall affect the authority of the Food and Drug Administration to request or participate in a voluntary recall, or to issue an order to cease distribution or to recall under any other provision of this chapter or under the Public Health Service Act.".

SEC. 106. LABELING.

(a) IN GENERAL.—Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 105, is further amended by adding at the end the following:

"SEC. 614. LABELING.

"(a) SAFETY REVIEW AND LABELING.—Following a review of cosmetic ingredients that determines that warnings are required to help ensure safe use of cosmetic prod-

ucts under section 608(d)(5), the Food and Drug Administration shall require labeling of cosmetics that are not appropriate for use in the entire population, including warnings that vulnerable populations, such as children or pregnant women, should limit or avoid using the product.

"(b) COSMETIC PRODUCTS FOR PROFESSIONAL USE.—

"(1) DEFINITION OF PROFESSIONAL.—With respect to cosmetics, the term 'professional' means an individual who—

"(A) is licensed by an official State authority to practice in the field of cosmetology, nail care, barbering, and or esthetics;

"(B) has complied with all requirements set forth by the State for such licensing; and

"(C) has been granted a license by a State board or legal agency or legal authority.

"(2) LISTING OF INGREDIENTS.—Cosmetic products used and sold by professionals shall list all ingredients, as required for other cosmetic products under this chapter.

"(3) PROFESSIONAL USE LABELING.—In the case of a cosmetic product intended to be used only by a professional on account of a specific ingredient or increased concentration of an ingredient that re-

quires safe handling by trained professionals, the product shall bear a statement as follows: 'To be Administered Only by Licensed Professionals'.

"(c) DISPLAY.—The warning required under subsection (a) and the statement required under subsection (b)(3) shall be prominently displayed—

"(1) in the primary language used on the label; and

"(2) in conspicuous and legible type in contrast by typography, layout, or color with other material printed or displayed on the label.

"(d) INTERNET SALES.—In the case of Internet sales of cosmetics, each Internet website offering cosmetic products for sale to consumers shall provide the same information that is included on the packaging of the cosmetic products as regularly available, and the warnings and statements described in subsection (c) shall be prominently and conspicuously displayed on the website.

"(e) CONTACT INFORMATION.—The label on each cosmetic shall bear the domestic telephone number or electronic contact information, and it is encouraged that the label include both the telephone number and electronic contact information, that consumers may use to contact the responsible person with respect to adverse events. The contact number shall provide a means for consumers to

obtain additional information about ingredients in a cosmetic, including the ability to ask if a specific ingredient may be present that is not listed on the label, including whether a specific ingredient may be contained in the fragrance or flavor used in the cosmetic. The manufacturer of the cosmetic is responsible for providing such information, including obtaining the information from suppliers if it is not readily available. Suppliers are required to release such information upon request of the cosmetic manufacturer.''.

(b) EFFECTIVE DATE.—Section 614 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall take effect on the date that is 1 year after the date of enactment of this Act.

SEC. 107. COAL TAR CHEMICALS.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 106, is further amended by adding at the end the following:

''SEC. 615. COAL TAR CHEMICALS.

''(a) IN GENERAL.—Under section 608, the Food and Drug Administration may review any cosmetic ingredient in order to determine if it is safe in cosmetic products without the need for specified conditions of use or tolerances, safe in cosmetic products under specified conditions of use or tolerances, or not safe in cosmetic products.

"(b) COAL TAR HAIR DYES.—Specific chemicals in coal tar hair dyes may be selected and reviewed under section 608(a)(3).".

SEC. 108. ANIMAL TESTING ALTERNATIVES.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 107, is further amended by adding the following:

"SEC. 616. ANIMAL TESTING ALTERNATIVES.

"(a) IN GENERAL.—To minimize the use of animal testing for safety of cosmetic ingredients, non-functional constituents, and finished cosmetic products, the Food and Drug Administration shall—

"(1) encourage the use of alternative testing methods that provide information that is equivalent or superior in scientific quality to the animal testing method to—

"(A) not involve the use of an animal to test a chemical substance for safe use in cosmetics; or

"(B) use fewer animals than conventional animal-based tests for safe use in cosmetics when nonanimal methods are impracticable; and

"(2) encourage—

"(A) the sharing of data across companies and organizations that are testing for safety in

cosmetics, so as to avoid duplication of animal tests; and

"(B) funding for research and validation of alternative testing methods.

"(b) GUIDANCE.—Not later than 3 years after the date of enactment of the Personal Care Products Safety Act, the Food and Drug Administration shall issue guidance on the acceptability of scientifically reliable and relevant alternatives to animal testing for the safety of cosmetic ingredients, non-functional constituents, and finished cosmetic products, and encouraging the use of such methods. The Food and Drug Administration shall update such guidance on an annual basis.

"(c) RESOURCES REGARDING ANIMAL TESTING ALTERNATIVES.—Not later than 180 days after the date of enactment of the Personal Care Products Safety Act, the Food and Drug Administration shall provide information on the Internet website of the Food and Drug Administration regarding resources available for information about non-animal methods, and methods that reduce animal usage, in testing for the safety of cosmetic ingredients, non-functional constituents, and finished cosmetic products.".

SEC. 109. PREEMPTION.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 108, is further amended by adding the following:

"SEC. 617. PREEMPTION.

"(a) REGISTRATION, GOOD MANUFACTURING PRACTICES, RECALLS, ADVERSE EVENT REPORTING.—Except for a State requirement that is in full effect and implemented on the date of enactment of the Personal Care Products Safety Act, no State or political subdivision of a State may establish or continue in effect any requirement for cosmetics with respect to registration, good manufacturing practices, mandatory recalls, or adverse event reporting.

"(b) SAFETY OF COSMETIC INGREDIENTS AND NONFUNCTIONAL CONSTITUENTS.—

"(1) IN GENERAL.—Except for a State requirement that is more restrictive than a final order issued under section 608(d)(3) and that is in full effect and implemented on the date of enactment of the Personal Care Products Safety Act, no State or political subdivision of a State may establish or continue in effect any requirement with respect to the safety of a cosmetic ingredient or non-functional constituent that is the subject of a final order under

section 608(d)(3) that is different from, or in addition to, a final order issued under section 608(d)(3).

"(2) DELAYED EFFECT OF NEW STATE REQUIREMENTS.—From the date that the Food and Drug Administration has made public the final selection of a cosmetic ingredient or non-functional constituent to be reviewed in the coming year under section 608(a)(3)(B), and opened the public comment period under section 608(a)(2), until the date that is one year after the Food and Drug Administration has made public such selection, no State or political subdivision of a State may establish any new requirement related to such cosmetic ingredient or non-functional constituent.

"(3) SCOPE.—This subsection shall not be construed to modify or affect the authority of a State or political subdivision of a State with respect to such safety requirements unrelated to the scope of the safety assessment under section 608.

"(4) SENSE OF CONGRESS.—It is the sense of Congress that a State or political subdivision that regulates the safety of cosmetics with respect to the health of humans beyond the scope of section 608 should utilize the safety assessment criteria described in section 608(h).

"(c) STATE REQUIREMENT THAT IS IN FULL EFFECT AND IMPLEMENTED.—For purposes of this section:

"(1) STATE REQUIREMENT.—A State requirement includes a State requirement that is adopted by a State public initiative or referendum.

"(2) FULL EFFECT AND IMPLEMENTED.—The term 'full effect and implemented' includes requirements of States that are implemented after the date of enactment of the Personal Care Products Safety Act, if such requirements are under a law that was in effect, or a lawful program that was established and functioning, prior to the date of enactment of the Personal Care Products Safety Act.

"(d) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—Notwithstanding any other provision of this Act, no provision of this chapter relating to a cosmetic shall be construed to modify or otherwise affect any action or the liability of any person under State or Federal common law.

"(e) LIMITATION.—The Personal Care Products Safety Act, including the amendments made by such Act, shall not be construed to preempt any State statute, public initiative, referendum, or common law, except as expressly provided in this section.".

SEC. 110. REPORTING.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 109, is further amended by adding at the end the following:

"SEC. 618. REPORTING.

"(a) PERFORMANCE REPORT.—Beginning with fiscal year 2016, and not later than 60 days prior to the end of each fiscal year for which fees are collected under section 744L, the Food and Drug Administration shall prepare and submit to Congress a report concerning the progress of the Food and Drug Administration in achieving the objectives of the Personal Care Products Safety Act during such fiscal year and the future plans of the Food and Drug Administration for meeting the objectives. The annual report for a fiscal year shall include—

"(1) the number of registered facilities and cosmetic ingredient statements on file with the Food and Drug Administration;

"(2) identification of the cosmetic ingredients and non-functional constituents that have been fully reviewed for safety by the Food and Drug Administration in the prior fiscal year and for which a final administrative order has been released;

"(3) identification of at least 5 specific cosmetic ingredients and non-functional constituents that will

be reviewed by the Food and Drug Administration in the next fiscal year;

"(4) the number of facilities inspected and mandatory recalls that transpired during that fiscal year;

"(5) the number of serious adverse event reports received by the Food and Drug Administration during that fiscal year;

"(6) any trends identified by the Food and Drug Administration about adverse event reports related to specific cosmetic ingredients or non-functional constituents; and

"(7) efforts of the Food and Drug Administration to reduce animal testing for safety of cosmetic ingredients, non-functional constituents, and cosmetic products.

"(b) PUBLIC AVAILABILITY.—The Food and Drug Administration shall make the reports required under subsections (a) available to the public on the Internet website of the Food and Drug Administration on the date of submission of such reports to Congress.

"(c) PUBLIC INPUT ON SAFETY REVIEW.—Upon release of the report described in subsection (a), the Food and Drug Administration shall provide the public with an opportunity to provide feedback on subsection (a)(3) by—

"(1) providing an electronic portal, upon release of the report, enabling the public to—

"(A) recommend additional cosmetic ingredients and non-functional constituents to be considered for review for safety in future years; and

"(B) comment on the priorities for the specific cosmetic ingredients and non-functional constituents that the Food and Drug Administration anticipates will be reviewed in the next fiscal year;

"(2) announcing on the Internet website of the Food and Drug Administration, within the first 30 days of the new fiscal year, any amendments to subsection (a)(3) based on public input, pursuant to paragraph (1); and

"(3) together with the final announcement of 5 specific cosmetic ingredients and non-functional constituents that will be reviewed in the coming year under subsection (a)(3), providing a comment period for further public input, pursuant to section 608(a)(2).".

SEC. 111. SMALL BUSINESSES.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 110, is further amended by adding at the end the following:

"SEC. 619. SMALL BUSINESSES.

"The Commissioner, in coordination with the Administrator of the Small Business Administration, shall provide technical assistance, such as guidance and expertise, to small businesses regarding compliance with the Personal Care Products Safety Act, including the amendments made by such Act.".

SEC. 112. APPLICABILITY WITH RESPECT TO CERTAIN COSMETICS.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 111, is further amended by adding at the end the following:

"SEC. 620. APPLICABILITY WITH RESPECT TO CERTAIN COSMETICS.

"In the case of a cosmetic product or a facility that is subject to the requirements under this chapter and chapter V, if any requirement under chapter V with respect to such cosmetic or facility is substantially similar to a requirement under this chapter, the cosmetic product or facility shall be deemed to be in compliance with the applicable requirement under this chapter if such product or facility is in compliance with such substantially similar

requirement under chapter V, provided that the product or facility has not obtained a waiver from the requirement under chapter V.".

SEC. 113. ENFORCEMENT.

(a) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended—

(1) in subsection (e)—

(A) by striking "504, 564" and inserting "504, 564, 611, or 612"; and

(B) by striking "519, 564" and inserting "519, 564, 611,";

(2) in subsection (j) by inserting "607, 608, 610," before "704";

(3) in subsection (ii)—

(A) by striking "760 or 761)" and inserting "604, 760, or 761)"; and

(B) by striking "760 or 761) submitted" and inserting "611, 760, or 761) submitted";

(4) in subsection (xx) by inserting "or 613" after "423"; and

(5) by adding at the end the following:

"(ddd) The failure to register in accordance with section 605, the failure to submit a cosmetic ingredient statement under section 606, the failure to provide any infor-

mation required by section 605 or 606, or the failure to update the information required by section 605 or 606, as required.".

(b) ADULTERATION.—Section 601 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361), as amended by section 103, is further amended by adding at the end the following:

"(g) If it contains, after the date prescribed under section 608(e), an ingredient that the Food and Drug Administration has determined under section 608(d)(4) to be not safe, or not safe under the conditions of use recommended or suggested in the label or a non-functional constituent that the Food and Drug Administration has determined under section 608(d)(4) to be not safe or not safe in the amount present in the cosmetic.

"(h) If it is a cosmetic product for which any requirement of section 609 (relating to safety substantiation) is not met.".

(c) MISBRANDING.—Section 602 is amended—

(1) in subsection (b)—

(A) by striking "and (2)" and inserting "(2)"; and

(B) by inserting "; and (3) a domestic address or a domestic telephone number, and it is encouraged that the label include both a domes-

tic address and a domestic telephone number, through which the responsible person may receive a report of an adverse event associated with the use of such cosmetic product'' after ''numerical count''; and

(2) by adding at the end the following:

''(g) If it has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the responsible person, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.

''(h) If its labeling does not conform with a requirement under section 614.''.

(d) GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Food and Drug Administration shall issue guidance that defines the circumstances that would constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, for purposes of section 602(g) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c)(2).

(e) IMPORTS.—Section 801(a) is amended—

(1) by striking ''section 760 or 761'' the first, third, and fourth place such term appears and inserting ''section 611, 760, or 761''; and

(2) by striking "760 or 761)" and inserting "604, 760, or 761)".

(f) FACTORY INSPECTION.—Section 704(a)(1) is amended by inserting after the third sentence the following: "In the case of any person who manufactures, processes, packs, holds, distributes, or imports a cosmetic product, or distributes a cosmetic product and affixes its name on the cosmetic label, the inspection shall extend to all records and other information described in section 612 (regarding inspection of cosmetic records), when the standard for records inspections under paragraph (1) or (2) of subsection (a) of such section applies, subject to the limitations under subsection (d) of such section.".

SEC. 114. CONSUMER INFORMATION.

The Food and Drug Administration shall post on its Internet website information for consumers regarding—

(1) final orders regarding the safety of a cosmetic ingredient or non-functional constituent under section 608(d)(3);

(2) cosmetic product recalls (including voluntary and mandatory recalls); and

(3) identified counterfeit cosmetic products.

TITLE II—FEES RELATED TO COSMETIC SAFETY

SEC. 201. FINDINGS.

Congress finds that the fees authorized by the amendments made by this title will be dedicated to cosmetic safety activities, as set forth in the goals identified for purposes of part 10 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee of Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee of on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 202. AUTHORITY TO ASSESS AND USE COSMETIC SAFETY FEES.

Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

"PART 10—FEES RELATING TO COSMETICS

"SEC. 744L. REGISTRATION FEE.

"(a) ASSESSMENT AND COLLECTION.—

"(1) IN GENERAL.—Beginning in fiscal year 2016, the Food and Drug Administration shall assess and collect an annual fee from every responsible

person (referred to in this section as a 'registrant') who owns or operates any cosmetic facility engaged in manufacturing or processing, or whose name and address appear on the label of a cosmetic product distributed in the United States, except that this subsection shall not apply to entities described in subparagraphs (A) through (H) of section 604(3).

"(2) PAYABLE DATE.—A fee under this section shall be payable during the period of initial registration and on the date of registration each year thereafter as prescribed in section 605(a)(1).

"(b) DEFINITIONS.—In this section:

"(1) ADJUSTMENT FACTOR.—The term 'adjustment factor' applicable to a fiscal year means the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such index for October 2015.

"(2) AFFILIATE.—The term 'affiliate' means any business entity that has a relationship with a second business entity if, directly or indirectly—

"(A) one business entity controls, or has power to control, the other business entity; or

"(B) a third-party controls, or has the power to control, both of the business entities.

"(3) COSMETIC SAFETY ACTIVITIES.—The term 'cosmetic safety activities'—

"(A) means activities related to compliance by registrants under section 605 with the requirements of this Act with respect to cosmetics, including—

"(i) administrative activities, such as information technology support, human resources, financial management, the administration and maintenance of the cosmetic registration system and the cosmetic ingredient statement system under sections 605 and 606, and fee assessment and collection under this section; and

"(ii) implementation and enforcement activities, such as the establishment of good manufacturing practices, the review of adverse event reports, inspection planning and inspections, and use of enforcement tools; and

"(B) includes activities related to implementation of section 608, regarding the review of cosmetic ingredients and non-functional constituents.

"(4) GROSS ANNUAL SALES.—The term 'gross annual sales' means the average United States gross annual sales for the previous 3-year period of cosmetics for a registrant, including the sales of all of its affiliates, as reported in the registration under section 605.

"(c) FEE SETTING AND AMOUNTS.—

"(1) IN GENERAL.—Subject to subsection (d), the Food and Drug Administration shall establish the fees to be collected under this section for each fiscal year after fiscal year 2016, based on the methodology described in paragraph (3)(B), and shall publish such fees in a Federal Register notice not later than 60 days before the beginning of each such fiscal year.

"(2) FEE EXEMPTION.—Any registrant whose average gross annual sales of cosmetic products in the 3-year period immediately preceding the fiscal year for which the annual fee will be paid was not more than $500,000, shall be exempt from registration fees under this section for that fiscal year.

"(3) ANNUAL FEE SETTING.—

"(A) FISCAL YEAR 2016.—For fiscal year 2016, to generate a total estimated revenue amount of $20,600,000, the amount of the reg-

istration fee under subsection (a) shall be as follows:

"(i) TIER I-A.—For a registrant that has gross annual sales of $5,000,000,000 or more in 2015, $1,100,000.

"(ii) TIER I-B.—For a registrant that has gross annual sales of at least $4,000,000,000 per annum but less than $5,000,000,000 in 2015, $840,000.

"(iii) TIER II-A.—For a registrant that has gross annual sales of at least $3,000,000,000 per annum but less than $4,000,000,000 in 2015, $720,000.

"(iv) TIER II-B.—For a registrant that has gross annual sales of at least $2,000,000,000 per annum but less than $3,000,000,000 in 2015, $600,000.

"(v) TIER III-A.—For a registrant that has gross annual sales of at least $1,000,000,000 per annum but less than $2,000,000,000 in 2015, $500,000.

"(vi) TIER III-B.—For a registrant that has gross annual sales of at least $500,000,000 per annum but less than $1,000,000,000 in 2015, $395,000.

"(vii) TIER IV-A.—For a registrant that has gross annual sales of at least $200,000,000 per annum but less than $500,000,000 in 2015, $325,000.

"(viii) TIER IV-B.—For a registrant that has gross annual sales of at least $100,000,000 per annum but less than $200,000,000 in 2015, $275,000.

"(ix) TIER V-A.—For a registrant that has gross annual sales of at least $80,000,000 per annum but less than $100,000,000 in 2015, $185,000.

"(x) TIER V-B.—For a registrant that has gross annual sales of at least $60,000,000 per annum but less than $80,000,000 in 2015, $95,000.

"(xi) TIER VI-A.—For a registrant that has gross annual sales of at least $40,000,000 per annum but less than $60,000,000 in 2015, $15,000.

"(xii) TIER IV-B.—For a registrant that has gross annual sales of at least $20,000,000 per annum but less than $40,000,000 in 2015, $12,000.

"(xiii) TIER VII-A.—For a registrant that has gross annual sales of at least $2,500,000 per annum but less than $20,000,000 in 2015, $500.

"(xiv) TIER VII-B.—For a registrant that has gross annual sales of at least $500,000 per annum but less than $2,500,000 in 2015, $250.

"(B) FISCAL YEARS 2017–2022.—For fiscal years 2017–2022, fees under subsection (a) shall be established to generate a total estimated revenue amount of $20,600,000, as adjusted by subsection (d). Of that amount:

"(i) TIER I-A.—Registrants that have gross annual sales of $5,000,000,000 or more in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 10.7 percent.

"(ii) TIER I-B.—Registrants that have gross annual sales of at least $4,000,000,000 per annum but less than $5,000,000,000 in the fiscal year immediately preceding the fiscal year in which

the annual fee will be paid, shall be responsible, collectively, for 4.1 percent.

"(iii) TIER II-A.—Registrants that have gross annual sales of at least $3,000,000,000 per annum but less than $4,000,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 3.5 percent.

"(iv) TIER II-B.—Registrants that have gross annual sales of at least $2,000,000,000 per annum but less than $3,000,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 2.9 percent.

"(v) TIER III-A.—Registrants that have gross annual sales of at least $1,000,000,000 per annum but less than $2,000,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 7.3 percent.

"(vi) TIER III-B.—Registrants that have gross annual sales of at least

$500,000,000 per annum but less than $1,000,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 13.4 percent.

"(vii) TIER IV-A.—Registrants that have gross annual sales of at least $200,000,000 per annum but less than $500,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 15.8 percent.

"(viii) TIER IV-B.—Registrants that have gross annual sales of at least $100,000,000 per annum but less than $200,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 13.3 percent.

"(ix) TIER V-A.—Registrants that have gross annual sales of at least $80,000,000 per annum but less than $100,000,000 in the fiscal year immediately preceding the fiscal year in which

the annual fee will be paid, shall be responsible, collectively, for 9 percent.

"(x) TIER V-B.—Registrants that have gross annual sales of at least $60,000,000 per annum but less than $80,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 6.9 percent.

"(xi) TIER VI-A.—Registrants that have gross annual sales of at least $40,000,000 per annum but less than $60,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 5.1 percent.

"(xii) TIER VI-B.—Registrants that have gross annual sales of at least $20,000,000 per annum but less than $40,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 4.4 percent.

"(xiii) TIER VII-A.—Registrants that have gross annual sales of at least

$2,500,000 per annum but less than $20,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 1.2 percent.

"(xiv) TIER VII-B.—Registrants that have gross annual sales of at least $500,000 per annum but less than $2,500,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 2.4 percent, except that no such registrant shall be responsible for more than $250 per fiscal year.

"(d) ADJUSTMENTS.—

"(1) INFLATION ADJUSTMENT.—

"(A) IN GENERAL.—For fiscal year 2017 and each subsequent fiscal year, the revenues and fee amounts under subsection (c)(3)(B) shall be adjusted by the Food and Drug Administration in the annual Federal Register notice establishing fees in subsection (c)(1), by an amount equal to the sum of—

"(i) one;

"(ii) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 of the preceding 4 fiscal years for which data are available, multiplied by the average proportion of personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 years of the preceding 4 fiscal years for which data are available; and

"(iii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC6 MD-VA-WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 years of the preceding 4 years for which data are available multiplied by the average proportion of all costs other than personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 years of the preceding 4 fiscal years for which data are available.

"(B) COMPOUNDED BASIS.—The adjustment made each fiscal year under this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2016 under this subsection.

"(2) FINAL YEAR ADJUSTMENT.—For fiscal year 2022, the Food and Drug Administration may, in addition to adjustments under paragraph (1), further increase the fee revenues and fees established in subsection (c) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover fees for cosmetic safety activities for the first 3 months of fiscal year 2023. If such an adjustment is necessary, the rationale for the increase, shall be contained in the annual Federal Register notice establishing fees, in subsection (c)(1), for fiscal year 2022. If the Food and Drug Administration has carryover balances for such activities in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

"(3) WORKLOAD ADJUSTMENT.—

"(A) IN GENERAL.—For fiscal year 2017 and each subsequent fiscal year, after fee reve-

nues established in subsection (c)(3)(B) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for each fiscal year to reflect changes in the workload of the Food and Drug Administration for actual changes in workload volume due to the process of reviewing cosmetic ingredients or non-functional constituents not listed under section 608(b).

"(B) DETERMINATION OF ADJUSTMENT.—The adjustment shall be determined by the Food and Drug Administration based on the workload in the most recent 1-year period for which workload data is available. The Food and Drug Administration shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

"(C) MINIMUM REVENUES.—The adjustment shall not result in fee revenues for a fiscal year that are less than the sum of the amount under subsection (c)(3)(B), as adjusted for inflation under subparagraph (1).

"(e) LIMITATIONS.—

"(1) IN GENERAL.—With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for the cosmetics program in the Center for Food Safety and Applied Nutrition and related field activities, fees may not be assessed under subsection (a) for the fiscal year unless the amount so appropriated for the fiscal year (excluding the amount of fees appropriated for the fiscal year), is equal to or greater than that assessed for fiscal year 2015, multiplied by the adjustment factor applicable to the fiscal year involved.

"(2) AUTHORITY.—If the Food and Drug Administration does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Food and Drug Administration may assess such fees, the Food and Drug Administration may assess and collect such fees, without any modification in the rate, for registration under section 605 at any time in such fiscal year.

"(f) CREDITING AND AVAILABILITY OF FEES.—

"(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided

in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for cosmetic safety activities.

"(2) COLLECTIONS AND APPROPRIATIONS ACTS.—The fees authorized by this section—

"(A) IN GENERAL.—Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year.

"(B) USE OF FEES AND LIMITATION.—The fees authorized by this section shall be collected and available only to defray the costs of cosmetic safety activities.

"(C) FEE COLLECTIONS DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through Sep-

tember 30, 2015, for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2016 may be collected and shall be credited to such account to remain available until expended. Fees collected under this subparagraph shall be considered discretionary for purposes of the Balanced Budget and Emergency Deficit Control Act of 1985.

"(D) REIMBURSEMENT OF START-UP AMOUNTS.—Any amounts allocated to establish programs under sections 605 and 606, prior to collection of fees, may be reimbursed through any appropriated fees collected under this section, in such manner as the Food and Drug Administration determines appropriate. Any amounts reimbursed under this subparagraph shall be available for the programs and activities for which funds allocated to establish the programs were available, prior to such allocation, until the end of the fiscal year in which the reimbursement occurs, notwithstanding any otherwise applicable limits on amounts for such program or activities for a fiscal year.

"(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2016–2022, there are authorized to be appropriated for fees under this section $20,600,000, as adjusted by subsection (d).

"(4) OFFSET OF OVERCOLLECTIONS; RECOVERY OF COLLECTION SHORTFALLS.—

"(A) OFFSET OF OVERCOLLECTIONS.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2016 through 2020 exceeds the cumulative amount appropriated pursuant to paragraph (3) for fiscal years 2016–2021, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2022.

"(B) RECOVERY OF COLLECTION SHORTFALLS.—

"(i) 2018.—For fiscal year 2018, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which

the amount collected under this section and appropriated for fiscal year 2016 falls below the amount of fees authorized for fiscal year 2016 under paragraph (3).

"(ii) 2019.—For fiscal year 2019, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2017 falls below the amount of fees authorized for fiscal year 2017 under paragraph (3).

"(iii) 2020.—For fiscal year 2020, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2018 falls below the amount of fees authorized for fiscal year 2018 under paragraph (3).

"(iv) 2021.—For fiscal year 2021, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section

and appropriated for fiscal year 2019 falls below the amount of fees authorized for fiscal year 2019 under paragraph (3).

"(v) 2022.—For fiscal year 2022, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2020 falls below the amount of fees authorized for fiscal year 2020 under paragraph (3).

"(g) EFFECT OF FAILURE TO PAY FEES.—The Food and Drug Administration shall not consider a registration submitted to be complete until such fee under subparagraph (a) is paid. Until the fee is paid, the registration is incomplete and the registrant is deemed to have failed to register in accordance with section 605.

"(h) FALSE STATEMENTS.—Any statement or representation made to the Food and Drug Administration shall be subject to section 1001 of title 18, United States Code.

"(i) COLLECTION OF UNPAID FEES.—In any case where the Food and Drug Administration does not receive payment of a fee assessed under subsection (a), such fee shall be treated as a claim of the United States Govern-

ment subject to subchapter II of chapter 37 of title 31, United States Code.

"(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in cosmetic activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

"(k) RECORDS.—Each facility shall retain all records necessary to demonstrate the facility's gross annual sales for at least 2 fiscal years after such information is reported in the facility's registration. Such records shall be made available to the Food and Drug Administration for review and duplication upon request of the Food and Drug Administration.".

SEC. 203. DIRECT HIRING AUTHORITY TO SUPPORT ACTIVITIES RELATED TO COSMETICS.

Part 10 of subchapter C of chapter VII, as added by section 202, is amended by inserting after section 744L the following:

"SEC. 744M. DIRECT HIRING AUTHORITY TO SUPPORT ACTIVITIES RELATED TO COSMETICS.

"(a) IN GENERAL.—The Food and Drug Administration shall have direct hiring authority with respect to the

appointment of employees into the competitive service or the excepted service to administer the amendments made by title I of the Personal Care Products Safety Act.

"(b) SUNSET.—The authority under subsection (a) shall terminate on the date that is 3 years after the date of enactment of such title.".

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 4/17/2015 3:11:56 PM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
Subject: FW: Proposed Changes to the Chemical Safety for the 21st Century Act - Response v 3.1
Attachments: Proposed Changes to the Chemical Safety for the 21st Century Act - Response v 3.1.rtf

FYI...

From: Black, Jonathan (Tom Udall)
Sent: Friday, April 17, 2015 11:10 AM
To: Enderle, Emily (Whitehouse); Deveny, Adrian (Merkley); Zipkin, Adam (Booker)
Cc: Karakitsos, Dimitri (EPW); Black, Jonathan (Tom Udall)
Subject: Proposed Changes to the Chemical Safety for the 21st Century Act - Response v 3.1

Emily, Adrian and Adam,

Due to the new mark-up schedule, we want to get you the response ASAP. We were still working through some stuff and hoped to have it resolved, but want to send you the latest thing.

We're going to review over the weekend to ensure we didn't make any mistakes. Please consider this a conditional offer while we get our ducks in a row for early next week.

I know Sen. Udall also wants to visit with your three bosses to discuss.

Dimitri is also going to send around a short two-page write-up to explain these response.

Title: To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act".

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(c) of the Toxic Substances Control Act (15 U.S.C. 2601(c)) is amended—

(1) by striking "It is the intent" and inserting the following:

"(1) ADMINISTRATION.—It is the intent";

(2) in paragraph (1) (as so redesignated), by inserting ", as provided under this Act" before the period at the end; and

(3) by adding at the following:

"(2) REFORM.—It is the intent of Congress that reform of this Act in accordance with the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act—

"(A) shall be administered in a manner that—

"(i) protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and

"(ii) ensures that appropriate information on chemical substances and mixtures is available to public health officials and first responders in the event of an emergency; and

"(B) shall not displace or supplant common law rights of action or remedies for civil relief.".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) by redesignating paragraphs (4), (5), (6), (7), (8), (9), (10), (11), (12), (13), and (14) as paragraphs (5), (6), (7), (8), (9), (10), (12), (13), (17), (18), and (19), respectively;

(2) by inserting after paragraph (3) the following:

"(4) CONDITIONS OF USE.—The term 'conditions of use' means the intended, known, or reasonably foreseeable circumstances the Administrator determines a chemical substance is manufactured, processed, distributed in commerce, used, or disposed of.";

(3) by inserting after paragraph (10) (as so redesignated) the following:

"(11) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.—The term 'potentially

exposed or susceptible population' means 1 or more groups—

"(A) of individuals within the general population who may be—

"(i) differentially exposed to chemical substances under the conditions of use; or

"(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

"(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; and

(4) by inserting after paragraph (13) (as so redesignated) the following:

"(14) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.

"(15) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the conditions of use.

"(16) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of harm to health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of harm to—

"(A) the general population; or

"(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

The Toxic Substances Control Act is amended by inserting after section 3 (15 U.S.C. 2602) the following:

"SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

"(a) Definition of Guidance.—In this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.

"(b) Deadline.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.

"(c) Use of Science.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance on the use of science in making decisions under sections 4, 4A, 5, and 6.

"(2) GOAL.—A goal of the policies and procedures described in paragraph (1) shall be to

make the basis of decisions clear to the public.

"(3) REQUIREMENTS.—The policies, procedures, and guidance issued under this section shall describe the manner in which the Administrator shall ensure that —

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;

"(B) to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.

"(e) Review.—Not later than 5 years after the date of enactment of this section, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(1) review the adequacy of any policies, procedures, and guidance developed under this section, including animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this Act; and

"(2) after providing public notice and an opportunity for comment, revise the policies, procedures, and guidance if necessary to reflect new scientific developments or understandings.

"(f) Sources of Information.—In making any decision with respect to a chemical substance under section 4, 4A, 5, or 6, the Administrator shall take into consideration information relating

to the hazards and exposures of a chemical substance under the conditions of use that is reasonably available to the Administrator, including information that is—

"(1) submitted to the Administrator pursuant to any rule, consent agreement, order, or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act, by—

"(A) manufacturers or processors of a substance;

"(B) the public;

"(C) other Federal departments or agencies; or

"(D) the Governor of a State or a State agency with responsibility for protecting health or the environment;

"(2) submitted to a governmental entity in any jurisdiction pursuant to a governmental requirement relating to the protection of health or the environment; or

"(3) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible by the Administrator.

"(g) Testing of Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator shall establish policies and procedures for the testing of chemical substances or mixtures under section 4.

"(2) GOAL.—A goal of the policies and procedures established under paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) CONTENTS.—The policies and procedures established under paragraph (1) shall—

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential;

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations;

"(C) require the Administrator to consult with the Director of the National Institute for Occupational Safety and Health prior to prescribing epidemiologic studies of employees; and

"(D) prior to **making a request or** adopting a requirement for testing using vertebrate animals, require the Administrator to take into consideration, as appropriate and to the extent practicable, reasonably available—

Commented [S1]: OK

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

"(iii) high-throughput screening methods and the prediction models of those methods; and

"(iv) scientifically reliable and relevant alternatives to tests on animals that

would provide equivalent information.

"(4) TIERED TESTING.—

"(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.

"(B) SCREENING-LEVEL TESTS.—

"(i) IN GENERAL.—The screening-level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.

"(ii) USE.—Screening-level tests shall be used—

"(I) to screen chemical substances or mixtures for potential adverse effects; and

"(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.

"(C) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for safety assessments or safety determinations, the Administrator may require more advanced tests for potential health or environmental effects or exposure potential.

"(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

"(h) Safety Assessments and Safety Determinations.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(C) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall identify the substances subject to safety assessments and safety determinations to be completed that year.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(A) IN GENERAL.—The Administrator shall establish, by rule, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

"(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

"(C) MINIMUM REQUIREMENTS.—At a minimum, the policies and procedures under this paragraph shall—

"(i) describe—

"(I) the manner in which the Administrator will identify informational needs and seek that information from the public;

"(II) the information (including draft safety assessments) that may be submitted by interested individuals or entities, including States; and

"(III) the criteria by which that information will be evaluated;

"(ii) require the Administrator—

"(I)(aa) to define the scope of the safety assessment and safety determination to be conducted under section 6, including the hazards, exposures, conditions of use, and potentially exposed and susceptible populations that the Administrator expects to consider in a safety assessment;

"(bb) to explain the basis for the scope of the safety assessment and safety determination; and

"(cc) to accept comments regarding the scope of the safety assessment and safety determination; and

"(II)(aa) to identify the items described in subclause (I) that the Administrator has considered in the final safety assessment; and

"(bb) to explain the basis for the consideration of those items;

"(iii) describe the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the conditions of use will be considered, and explain the basis for that consideration in the final safety assessment;

"(iv) require that each safety assessment and safety determination shall include—

"(I) a description of the weight of the scientific evidence of risk; and

"(II) a summary of the information regarding the impact on health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies;

"(v) establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination; and

"(vi) when relevant information is provided or otherwise made available to the Administrator, shall consider the extent of Federal regulation under other Federal

laws.

"(D) GUIDANCE.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop guidance to assist interested persons in developing draft safety assessments and other information for submission to the Administrator, which may be considered at the discretion of the Administrator.

"(ii) REQUIREMENT.—The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing a draft assessment for consideration by the Administrator.

~~"(3) Articles. If the Administrator intends to prohibit or otherwise restrict an article on the basis of a chemical substance contained in that article, the Administrator shall have evidence of significant exposure to the chemical substance from such article.~~

Commented [S2]: OK – Please review proposed articles language intended to replace. New Section 6(d)(2)(C).

"(i) Publicly Available Information.—Subject to section 14, the Administrator shall—

"(1) make publicly available a nontechnical summary, and the final version, of each safety assessment and safety determination;

"(2) provide public notice and an opportunity for comment on each proposed safety assessment and safety determination; and

"(3) make public in a final safety assessment and safety determination—

"(A) the list of studies considered by the Administrator in carrying out the safety assessment or safety determination; and

"(B) the list of policies, procedures, and guidance that were followed in carrying out the safety assessment or safety determination.

"(j) Consultation With Science Advisory Committee on Chemicals.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish an advisory committee, to be known as the 'Science Advisory Committee on Chemicals' (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, on the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(5) RELATIONSHIP TO OTHER LAW.—All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).".

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking subsections (a), (b), (c), (d), and (g);

(2) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively;

(3) in subsection (f) (as so redesignated)—

(A) by striking "rule" each place it appears and inserting "rule, testing consent agreement, or order";

(B) by striking "under subsection (a)" each place it appears and inserting "under this subsection"; and

(C) in paragraph (1)(B), in the last sentence, by striking "rulemaking";

(4) in subsection (g) (as so redesignated)—

(A) in the first sentence, by striking "from cancer, gene mutations, or birth defects"; and

(B) by striking the last sentence; and

(5) by inserting before subsection (f) (as so redesignated) the following:

"(a) Development of New Information on Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section if the Administrator determines that the information is necessary—

"(A) to review a notice under section 5(d) or to perform a safety assessment or safety determination under section 6;

"(B) to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4) or under a rule promulgated under section 6(d)(3);

"(C) pursuant to section 12(a)(4); or

"(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

"(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.

"(B) PROHIBITION.—Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.

"(C) LIMITATION.—The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

"(3) FORM.—Subject to section 3A(h), the Administrator may require the development of information described in paragraph (1) or (2) by—

"(A) promulgating a rule;

"(B) entering into a testing consent agreement; or

"(C) issuing an order.

"(4) CONTENTS.—

"(A) IN GENERAL.—A rule, testing consent agreement, or order issued under this subsection shall include—

"(i) identification of the chemical substance or mixture for which testing is required;

"(ii) identification of the persons required to conduct the testing;

"(iii) test protocols and methodologies for the development of test data and information for the chemical substance or mixture, including specific reference to reliable nonanimal test procedures; and

"(iv) specification of the period within which individuals and entities required to conduct the testing shall submit to the Administrator the information developed in accordance with the procedures described in clause (iii).

"(B) CONSIDERATIONS.—In determining the procedures and period to be required under subparagraph (A), the Administrator shall take into consideration—

"(i) the relative costs of the various test protocols and methodologies that may be required; and

"(ii) the reasonably foreseeable availability of facilities and personnel required to perform the testing.

"(b) Statement of Need.—

"(1) IN GENERAL.—In promulgating a rule, entering into a testing consent agreement, or issuing an order for the development of additional information (including information on exposure or exposure potential) pursuant to this section, the Administrator shall—

"(A) identify the need intended to be met by the rule, agreement, or order;

"(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of vertebrate animals.

"(2) EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an order is warranted instead of promulgating a rule or entering into a testing consent agreement.

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a

description of—

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

"(ii) the extent to which the Administrator has obtained or attempted to obtain the information through voluntary submissions; and

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

"(I) animal-based studies; and

"(II) emerging methods and models; and

"(B) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and after providing an opportunity for public comment, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information under this title that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) as practicable, ensure that the strategic plan developed under subparagraph (A)

Commented [S3]: Additional request of Sen. Booker, not included in original offer. Suggest two years to be consistent with the same pace of other procedures.

Formatted: Superscript

is reflected in the development of requirements for testing under this section;

"(C) **identify in the strategic plan developed under subparagraph (A) alternative test methods or testing strategies that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information** of **equivalent** scientific reliability and quality **to that which would be obtained from vertebrate animal testing;**

Commented [S4]: OK with modification

"(D) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation; and

~~"(D)~~**"(E)** fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing under this title.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(4) VOLUNTARY TESTING.—~~No~~ Any **person** ~~may conduct new vertebrate animal testing for the purpose of~~ **developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator** shall, prior to conducting new vertebrate animal testing, consider whether if—

"(A) **the information could potentially be obtained by a test method or testing strategy that the Administrator determines under paragraph (2)(C) to be scientifically reliable, relevant, and capable of providing equivalent information;** and

~~"(B) the person has not first attempted to develop the information by means of that test method or testing strategy.~~

"(d) Testing Requirements.—

Commented [S5]: OK with modification. Cannot mandate how to do voluntary testing.

"(1) IN GENERAL.—The Administrator may require the development of information by—

"(A) manufacturers and processors of the chemical substance or mixture; and

"(B) persons that begin to manufacture or process the chemical substance or mixture—

"(i) after the effective date of the rule, testing consent agreement, or order; but

"(ii) subject to paragraph (3), before the period ending on the date that is 180 days after the end of the period described in this section.

"(2) DESIGNATION.—The Administrator may permit 2 or more persons identified in subparagraph (A) or (B) of paragraph (1) to designate 1 of the persons or a qualified third party—

"(A) to develop the information; and

"(B) to submit the information on behalf of the persons making the designation.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—A person otherwise subject to a rule, testing consent agreement, or order under this section may submit to the Administrator an application for an exemption on the basis that the information is being developed by a person designated under paragraph (2).

"(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

"(i) IN GENERAL.—If the Administrator accepts an application submitted under subparagraph (A), the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as agreed to between the applicant and the designee.

"(ii) ARBITRATION.—If the applicant and a person designated under paragraph (2) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.

"(C) TERMINATION.—If, after granting an exemption under this paragraph, the Administrator determines that a person covered by the exemption has failed to comply with the rule, testing consent agreement, or order, the Administrator shall—

"(i) by order, terminate the exemption; and

"(ii) notify in writing each person that received an exemption of the requirements with respect to which the exemption was granted.

"(e) Transparency.—Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders and all information submitted under this section.".

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the third sentence by striking "section 4(e)" and inserting "section 4(f)".

SEC. 6. PRIORITIZATION SCREENING.

The Toxic Substances Control Act is amended by inserting after section 4 (15 U.S.C. 2603) the following:

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) Establishment and List of Substances.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish, by rule, a risk-based screening process and explicit criteria for identifying existing chemical substances that are—

"(A) a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances'); and

"(B) a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').

"(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(A) IN GENERAL.—Before the date of promulgation of the rule under paragraph (1) and not later than 180 days after the date of enactment of this section, the Administrator—

"(i) shall take into consideration and publish an initial list of high-priority substances and low-priority substances; and

"(ii) pursuant to section 6(b), may initiate or continue safety assessments and safety determinations for those high-priority substances.

"(B) REQUIREMENTS.—

"(i) IN GENERAL.—The initial list of chemical substances shall contain at least 10 high-priority substances, at least 5 of which are drawn from the list of chemical substances identified by the Administrator in the October, 2014 TSCA Work Plan and subsequent updates, and at least 10 low-priority substances.

"(ii) SUBSEQUENTLY IDENTIFIED SUBSTANCES.—Insofar as possible, at least 50 percent of all substances subsequently identified by the Administrator as high-priority substances shall be drawn from the list of chemical substances identified by the Administrator in the October, 2014 TSCA Work Plan and subsequent updates, until all Work Plan chemicals have been designated under this subsection.

(iii) Persistence and Bioaccumulation.—In developing the initial list and in identifying additional high priority substances, the Administrator shall give preference to chemical substances scored as high for persistence and bioaccumulation in the October, 2014 TSCA Work Plan and subsequent updates.

Commented [S6]: Added to address concern over PBTs raised in Safer Chemicals, Healthy Families coalition statement

"(C) ADDITIONAL CHEMICAL REVIEWS.—The Administrator shall—

"(i) 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 20 high-priority substances have undergone or are

undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 20 low-priority substances have been designated; and

"(ii) as soon as practicable and not later than 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 25 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 25 low-priority substances have been designated.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator shall take into consideration active substances, as determined under section 8, which may include chemical substances on the interim list of active substances established under that section.

"(ii) INACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator may take into consideration inactive substances, as determined under section 8, that the Administrator determines—

"(I)(aa) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) have the potential for high hazard and widespread exposure; or

"(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) with respect to which there exists the potential for residual high hazards or widespread exposures not otherwise addressed by the regulatory or other action.

"(iii) REPOPULATION.—

"(I) IN GENERAL.—On the completion of a safety determination under section 6 for a chemical substance, the Administrator shall remove the chemical substance from the list of high-priority substances established under this subsection.

"(II) ADDITIONS.—The Administrator shall add at least 1 chemical substance to the list of high-priority substances for each chemical substance removed from the list of high-priority substances established under this subsection, until a safety assessment and safety determination is completed for all high-priority substances.

"(III) LOW-PRIORITY SUBSTANCES.—If a low-priority substance is subsequently designated as a high-priority substance, the Administrator shall remove that substance from the list of low-priority substances.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) not later than 180 days after the effective date of the final rule under paragraph (1), begin the prioritization screening process; and

"(II) make every effort to complete the designation of all active substances as high-priority substances or low-priority substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical substance as a high-priority substance or low-priority substance.

"(iii) CONSIDERATION.—

"(I) IN GENERAL.—The Administrator shall screen substances and designate high-priority substances taking into consideration the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in a timely manner.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.

"(C) SCREENING OF CATEGORIES OF SUBSTANCES.—The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate designations of high-priority substances and low-priority substances and safety assessments and safety determinations for high-priority substances.

"(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—Not less frequently than once each year, the Administrator shall publish a list of chemical substances that—

"(i) are being considered in the prioritization screening process and the status of the chemical substances in the prioritization process, including those chemical substances for which prioritization decisions have been deferred; and

"(ii) are designated as high-priority substances or low-priority substances, including the bases for such designations.

"(4) CRITERIA.—The criteria described in paragraph (1) shall account for—

"(A) the recommendation of the Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances appropriate for prioritization screening;

"(B) the hazard and exposure potential of the chemical substance (or category of substances), including persistence, bioaccumulation, and specific scientific classifications and designations by authoritative governmental entities;

Commented [S7]: Added to address concern with PBTs raised in Safer Chemicals, Healthy Families Coalition letter

"(C) the conditions of use or significant changes in the conditions of use of the chemical substance;

"(D) evidence and indicators of exposure potential to humans or the environment

from the chemical substance, including potentially exposed or susceptible populations;

"(E) the volume of a chemical substance manufactured or processed;

"(F) whether the volume of a chemical substance as reported under a rule promulgated pursuant to section 8(a) has significantly increased or decreased during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance;

"(G) the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

"(H) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a high-priority or a low-priority substance.

Commented [S8]: Suggested addition to neutralize preference for low-priority. This update was missed after low-priority pre-emption was eliminated

"(b) Prioritization Screening Process and Decisions.—

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall include a requirement that the Administrator shall—

"(A) identify the chemical substances being considered for prioritization;

"(B) request interested persons to supply information regarding the chemical substances being considered;

"(C) apply the criteria identified in subsection (a)(4); and

"(D) subject to paragraph (5) and using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.

"(2) INTEGRATION OF INFORMATION.—The prioritization screening decision regarding a chemical substance shall integrate any hazard and exposure information relating to the chemical substance that is available to the Administrator.

"(3) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(A) shall identify as a high-priority substance a chemical substance that, relative to other active chemical substances, the Administrator determines has the potential for high hazard and widespread exposure;

"(B) may identify as a high-priority substance a chemical substance that, relative to other active chemical substances, the Administrator determines has the potential for high hazard or widespread exposure; and

Commented [S9]: Suggest adding "active" to qualify the chemical substances on the "active" inventory.

"(C) may identify as a high-priority substance an inactive substance, as determined under subsection (a)(3)(A)(ii) and section 8(b), that the Administrator determines warrants a safety assessment and safety determination under section 6.

"(4) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as

a low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that the chemical substance is likely to meet the ~~applicable~~ safety standard.

Commented [S10]: Suggested deletion for clarification. "Applicable" not needed.

"(5) DEFERRING A DECISION.—If the Administrator determines that additional information is required to establish the priority of a chemical substance under this section, the Administrator may defer the prioritization screening decision for a reasonable period—

"(A) to allow for the submission of additional information by an interested person and for the Administrator to evaluate the additional information; or

"(B) to require the development of information pursuant to a rule, testing consent agreement, or order issued under section 4(a)(2).

"(6) DEADLINES FOR SUBMISSION OF INFORMATION.—If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of the information.

"(7) NOTICE AND COMMENT.—The Administrator shall—

"(A) publish the proposed decisions made under paragraphs (3), (4), and (5) and the basis for the decisions; and

"(B) provide an opportunity for public comment.

"(8) REVISIONS OF PRIOR DESIGNATIONS.—

"(A) IN GENERAL.—At any time, and at the discretion of the Administrator, the Administrator may revise the designation of a chemical substance as a high-priority substance or a low-priority substance based on information available to the Administrator after the date of the determination under paragraph (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.

"(9) OTHER INFORMATION RELEVANT TO PRIORITIZATION.—

"(A) IN GENERAL.—If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State proposes an administrative action or enacts a statute or takes an administrative action to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not as designated a high-priority substance, the Governor or State agency with responsibility for implementing the statute or administrative action shall notify the Administrator.

"(B) REQUESTS FOR INFORMATION.—Following receipt of a notification provided under subparagraph (A), the Administrator may request any available information from the Governor or the State agency with respect to—

"(i) scientific evidence related to the hazards, exposures and risks of the chemical substance under the conditions of use which the statute or administrative action is intended to address;

"(ii) any State or local conditions which warranted the statute or administrative action;

"(iii) the statutory or administrative authority on which the action is based; and

"(iv) any other available information relevant to the prohibition or other restriction, including information on any alternatives considered and their hazards, exposures, and risks.

"(C) PRIORITIZATION SCREENING.—The Administrator shall conduct a prioritization screening under this subsection for all substances that—

"(i) are the subject of notifications received under subparagraph (A); and

"(ii) the Administrator determines—

"(I) are likely to have significant health or environmental impacts;

"(II) are likely to have significant impact on interstate commerce; or

"(III) have been subject to a prohibition or other restriction under a statute or administrative action in 2 or more States.

"(D) AVAILABILITY TO PUBLIC.—Subject to section 14 and any applicable State law regarding the protection of confidential information provided to the State or to the Administrator, the Administrator shall make information received from a Governor or State agency under subparagraph (A) publicly available.

"(E) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall preempt a State statute or administrative action, require approval of a State statute or administrative action, or apply section 15 to a State.

"(10) REVIEW.—Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Administrator shall—

"(A) review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and

"(B) if necessary, modify the prioritization screening process.

"(11) ~~EFFECT.—SUBJECT TO SECTION 18, A~~ **EFFECT.—A** designation by the Administrator under this section with respect to a chemical substance shall not affect—

Commented [S11]: Not OK – AAJ supported text.

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance; or

"(B) the regulation of those activities.

"(c) Additional Priorities for Safety Assessments and Determinations.—

Commented [S12]: Suggested additions below proposed by Sen. Vitter.

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall—

"(A) include a process by which a manufacturer or processor of an active chemical substance that has not been designated a high-priority substance~~, or that has not been subject to or is not in the process of a prioritization screening by the Administrator~~,

may request that the Administrator designate the substance as an additional priority for a safety assessment and safety determination, subject to the payment of fees pursuant to section 26(b)(3)(E); and

"(B) specify ~~provide guidance to submitters on~~ the information to be provided in such requests, and

"(C) specify the criteria the Administrator shall use to determine whether or not to grant such a request, which shall include whether the substance is subject to restrictions imposed by statutes enacted or administrative actions taken by 1 or more States on the manufacture, processing, distribution in commerce, or use of the substance.

"(2) PREFERENCE.—Subject to paragraph (3), in deciding whether to grant requests under this subsection the Administrator shall give a preference to requests concerning substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

"(3) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

"(A) if a sufficient number of additional priority requests meet the requirements of paragraph (1), not ~~more~~less than 15 percent, and not more than 20 percent, of the total number of substances designated to undergo safety assessments and safety determinations under this section are substances designated under the process and criteria pursuant to paragraph (1); and

"(B) the resources allocated to conducting safety assessments and safety determinations for additional priorities designated under this subsection are proportionate to the number of such substances relative to the total number of substances designated to undergo safety assessments and safety determinations under this section.

"(4) REQUIREMENTS.—

"(A) IN GENERAL.—The public shall be provided notice and an opportunity to comment on requests submitted under this subsection.

"(B) DECISION BY ADMINISTRATOR.—Not later than 180 days after the date on which the Administrator receives a request under this subsection, the Administrator shall decide whether or not to grant the request.

"(C) ASSESSMENT AND DETERMINATION.—If the Administrator grants a request under this subsection, the safety assessment and safety determination—

"(i) shall be conducted in accordance with the deadlines and other requirements of sections 3A(i) and 6; and

"(ii) shall not be expedited or otherwise subject to special treatment relative to high-priority substances designated pursuant to subsection (b)(3) that are undergoing safety assessments and safety determinations.

"(5) EXCEPTIONS.—Requests granted under this subsection shall not be subject to

subsection ~~(a)(3)(A)(iii) or section 18(b).~~ **(a)(3)(A)(iii).”**.

Commented [S13]: Conforming change not OK.

SEC. 7. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) by striking the section designation and heading and inserting the following:

“SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.”;

(2) by striking subsection (b);

(3) by redesignating subsection (a) as subsection (b);

(4) by redesignating subsection (i) as subsection (a) and moving the subsection so as to appear at the beginning of the section;

(5) in subsection (b) (as so redesignated)—

(A) in the subsection heading, by striking “In General” and inserting “Notices”; and

(B) in paragraph (1), in the matter following subparagraph (B)—

(i) by striking “subsection (d)” and inserting “subsection (b)”; and

(ii) by striking “and such person complies with any applicable requirement of subsection (b)”;

(6) by redesignating subsections (c) and (d) as subsection (d) and (c), respectively, and moving subsection (c) (as so redesigned) so as appear after subsection (b) (as redesignated by paragraph (3));

(7) in subsection (c) (as so redesignated)—

(A) by striking paragraph (1) and inserting the following:

“(1) IN GENERAL.—The notice required by subsection (a) shall include, with respect to a chemical substance—

“(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

“(B) information regarding conditions of use and reasonably anticipated exposures.”;

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking “or of data under subsection (b)”;

(ii) in subparagraph (A), by adding “and” after the semicolon at the end;

(iii) in subparagraph (B), by striking “; and” and inserting a period; and

(iv) by striking subparagraph (C); and

(C) in paragraph (3), by striking "subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "subsection (b) and for which the notification period prescribed by subsection (b) or (d)";

(8) by striking subsection (d) (as redesignated by paragraph (6)) and inserting the following:

"(d) Review of Notice.—

"(1) INITIAL REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall—

"(i) conduct an initial review of the notice;

"(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

"(iii) make any necessary determination under paragraph (3).

"(B) EXTENSION.—Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.

"(2) INFORMATION SOURCES.—In evaluating a notice under paragraph (1), the Administrator shall take into consideration—

"(A) any relevant information identified in subsection (c)(1); and

"(B) any other relevant additional information available to the Administrator.

"(3) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), based on the information described in paragraph (2), and subject to section ~~18(g)~~ **18(f)**, the Administrator shall determine that—

Commented [S14]: Conforming change not OK.

"(A) the relevant chemical substance or significant new use is not likely to meet the safety standard, in which case the Administrator shall take appropriate action under paragraph (4);

"(B) the relevant chemical substance or significant new use is likely to meet the safety standard, in which case the Administrator shall allow the review period to expire without additional restrictions; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (5).

"(4) RESTRICTIONS.—

"(A) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—If the Administrator makes a determination under subparagraph (A) or (C) of paragraph (3) with respect to a notice submitted under subsection (b)—

"(I) the Administrator, before the end of the applicable period for review

under paragraph (1) and by consent agreement or order, as appropriate, shall prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the restrictions specified in the consent agreement or order that the Administrator determines are sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard; and

"(II) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, except in compliance with the restrictions specified in the consent agreement or order.

"(ii) LIKELY TO MEET STANDARD.—If the Administrator makes a determination under subparagraph (B) of paragraph (3) with respect to a chemical substance or significant new use for which a notice was submitted under subsection (b), at the end of the applicable period for review under paragraph (1), the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use.

"(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall—

"(i) take into consideration whether to promulgate a rule pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance, or of the chemical substance for a new use, that is not in compliance with the restrictions imposed by the consent agreement or order; and

"(ii)(I) initiate a rulemaking described in clause (i); or

"(II) publish a statement describing the reasons of the Administrator for not initiating a rulemaking.

"(C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include, as appropriate—

"(i) subject to section ~~18(g)~~ **18(f)**, a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator

Commented [S15]: Conforming change not OK.

"(ii) a requirement that manufacturers or processors of the chemical substance shall—

"(I) make and retain records of the processes used to manufacture or process, as applicable, the chemical substance; or

"(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, use, or disposal, as applicable, of the chemical substance, subject

to section 4;

"(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

"(I) in general; or

"(II) for a particular use;

"(iv) a prohibition or other restriction of—

"(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

"(II) any method of commercial use of the chemical substance; or

"(III) any method of disposal of the chemical substance; or

"(v) a prohibition or other restriction on the manufacture, processing, or distribution in commerce of the chemical substance—

"(I) in general; or

"(II) for a particular use.

"(D) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(E) DEFINITION OF REQUIREMENT.—For purposes of this Act, the term 'requirement' as used in this section does not displace common law.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

"(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(C) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

"(D) on receipt of information the Administrator finds supports the determination under paragraph (3), shall promptly make the determination.";

(9) by striking subsections (e) through (g) and inserting the following:

"(e) Notice of Commencement.—

"(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—

"(A) the name of the manufacturer; and

"(B) the initial date of nonexempt commercial manufacture.

"(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

"(f) Further Evaluation.—The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—

"(1) a notice of commencement for a chemical substance under subsection (c); or

"(2) new information regarding the chemical substance.

"(g) Transparency.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, consent agreements, rules, and orders of the Administrator; and

"(2) all information submitted or issued under this section."; and

(10) in subsection (h)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking "(a) or";

(B) by striking paragraph (2);

(C) by redesignating paragraphs (3) through (6) as paragraphs (2) through (5), respectively;

(D) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking "subsections (a) and (b)" and inserting "subsection (b)";

(E) in paragraph (3) (as so redesignated)—

(i) in the first sentence, by striking "will not present an unreasonable risk of injury to health or the environment" and inserting "will meet the safety standard"; and

(ii) by striking the second sentence;

(F) in paragraph (4) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (b)"; and

(G) in paragraph (5) (as so redesignated), in the first sentence, by striking "paragraph (1) or (5)" and inserting "paragraph (1) or (4)".

SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY

DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections (g) and (h), respectively;

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) shall, as soon as practicable and not later than 6 months after the date on which a chemical substance is designated as a high-priority substance, define the scope of the safety assessment and safety determination to be conducted pursuant to this section, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that the Administrator expects to consider;

"(3) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(4) shall complete a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

"(5) shall promulgate a final rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; and

"(6) may extend any deadline under this subsection for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under paragraphs (4) and (5) and any deferral under subsection (c)(2) does not exceed 2 years.

"(b) Prior Actions.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination that was initiated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, prior to the effective date of the policies and procedures required to be established by the Administrator under section 3A or 4A.

"(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or rule solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure.

"(c) Safety Determinations.—

"(1) IN GENERAL.—Based on a review of the information available to the Administrator, including draft safety assessments submitted by interested persons, and subject to section 18, the Administrator shall determine that—

"(A) the relevant chemical substance meets the safety standard;

"(B) the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by rule under subsection (d)—

"(i) impose restrictions necessary to ensure that the chemical substance meets the safety standard under the conditions of use; or

"(ii) if the safety standard cannot be met with the application of restrictions, ban or phase out the chemical substance, as appropriate; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is necessary to make a safety assessment or safety determination for a high-priority substance, the Administrator—

"(A) shall provide an opportunity for interested persons to submit the additional information;

"(B) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

"(C) may defer, for a reasonable period consistent with the deadlines described in subsection (a), a safety assessment and safety determination until after receipt of the information; and

"(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety determination, shall make a determination under paragraph (1).

"(3) ESTABLISHMENT OF DEADLINE.—In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.

"(d) Rule.—

"(1) IMPLEMENTATION.—If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a rule establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

"(2) SCOPE.—The rule promulgated pursuant to this subsection—

"(A) may—

"(i) apply to mixtures containing the chemical substance, as appropriate; and

"(ii) exempt replacement parts for articles manufactured prior to the applicable

Formatted: Indent: Before: 0.67"

compliance deadline; and

"(B) shall include dates by which compliance is mandatory, which—

"(i) shall be as soon as practicable; and

"(ii) as determined by the Administrator, may vary for different affected persons.

"(C) shall—

"(i) exempt replacement parts that are manufactured prior to the effective date of the rule for articles that are first manufactured prior to the effective date of the rule unless the Administrator finds such replacement parts contribute significantly to the identified risk; and

"(ii) in selecting among prohibitions and restrictions to address an identified risk, apply prohibitions or restrictions to articles on the basis of a chemical substance or mixture contained in the article only to the extent necessary to mitigate the identified risk.".

"(C D) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(D E) DEFINITION OF REQUIREMENT.—For the purposes of this Act, the term 'requirement' as used in this section does not displace common law.

"(3) RESTRICTIONS.—A restriction under paragraph (1) may include, as appropriate—

"(A) subject to section 18, a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator;

"(B) a requirement that manufacturers or processors of the chemical substance shall—

"(i) make and retain records of the processes used to manufacture or process the chemical substance;

"(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or

"(iii) monitor or conduct tests that are reasonably necessary to ensure compliance with the requirements of any rule under this subsection;

"(C) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

"(D) a requirement to ban or phase out, or any other rule regarding, the manufacture, processing, or distribution in commerce of the chemical substance for—

"(i) a particular use;

Commented [S16]: Suggested deletion to conform for new addition on articles below.

Commented [S17]: Suggested new provisions on "articles" taken from House Discussion Draft. EPA testified that this is OK and confirmed through technical assistance.

"(ii) a particular use at a concentration in excess of a level specified by the Administrator; or

"(iii) all uses;

"(E) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—

"(i) a particular use; or

"(ii) a particular use at a concentration in excess of a level specified by the Administrator;

"(F) a requirement to ban, phase out, or otherwise restrict any method of commercial use of the chemical substance;

"(G) a requirement to ban, phase out, or otherwise restrict any method of disposal of the chemical substance or any article containing the chemical substance; and

"(H) a requirement directing manufacturers or processors of the chemical substance to give notice of the Administrator's determination under subsection (c)(1)(B) to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

"(5) EXEMPTIONS.—

"(A) IN GENERAL.—The Administrator may exempt 1 or more uses of a chemical substance from any restriction in a rule promulgated under paragraph (1) if the Administrator determines that—

"(i) the rule cannot be complied with, without—

"(I) harming national security;

"(II) causing significant disruption in the national economy due to the lack of availability of a chemical substance; or

"(III) interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or

"(ii) the use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

"(B) EXEMPTION ANALYSIS.—In proposing a rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall make publicly available any analysis conducted under this paragraph to assess the need for the exemption.

"(C) STATEMENT REQUIRED.—In making final a rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall include a statement describing how the analysis considered under subparagraph (B) was taken into account.

"(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—In determining whether an exemption should be granted under this paragraph for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more technically and economically feasible alternatives to the chemical substance most likely to be used in place of the chemical substance under the conditions of use if the rule is promulgated.

"(E) CONDITIONS.—As part of a rule promulgated under paragraph (1), the Administrator shall include conditions in any exemption established under this paragraph, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption.

"(F) DURATION.—

"(i) IN GENERAL.—The Administrator shall establish, as part of a rule under paragraph (1) that contains an exemption under this paragraph, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis.

"(ii) AUTHORITY OF ADMINISTRATOR.—The Administrator, by rule, may extend, modify, or eliminate the exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or is no longer necessary.

"(iii) CONSIDERATIONS.—

"(I) IN GENERAL.—Subject to subclause (II), the Administrator shall issue exemptions and establish time periods by considering factors determined by the Administrator to be relevant to the goals of fostering innovation and the development of alternatives that meet the safety standard.

"(II) LIMITATION.—Any renewal of an exemption in the case of a rule requiring the ban or phase-out of a chemical substance shall not exceed 5 years.

"(e) Immediate Effect.—The Administrator may declare a proposed rule under subsection (d) to be effective on publication of the rule in the Federal Register and until the effective date of final action taken respecting the rule, if—

"(1) the Administrator determines that—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to the proposed rule or any combination of those activities is likely to result in an unreasonable risk of serious or widespread harm to health or the environment before the effective date; and

"(B) making the proposed rule so effective is necessary to protect the public interest; and

"(2) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under paragraph (1)(A), a court has granted relief in an action under section 7 with respect to that risk associated with the chemical substance or mixture.

"(f) Final Agency Action.—Under this section and subject to section 18—

"(1) a safety determination, and the associated safety assessment, for a chemical substance that the Administrator determines under subsection (c) meets the safety standard, shall be considered to be a final agency action, effective beginning on the date of issuance of the final safety determination; and

"(2) a final rule promulgated under subsection (d), and the associated safety assessment and safety determination that a chemical substance does not meet the safety standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule."; and

(4) in subsection (g) (as redesignated by paragraph (2))—

(A) by striking paragraph (4); and

(B) by redesignating paragraph (5) as paragraph (4).

SEC. 9. IMMINENT HAZARDS.

Section 7 of the Toxic Substances Control Act (15 U.S.C. 2606) is amended—

(1) by striking subsection (a) and inserting the following:

"(a) Civil Actions.—

"(1) IN GENERAL.—The Administrator may commence a civil action in an appropriate United States district court for—

"(A) seizure of an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture;

"(B) relief (as authorized by subsection (b)) against any person that manufactures,

processes, distributes in commerce, uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture; or

"(C) both seizure described in subparagraph (A) and relief described in subparagraph (B).

"(2) RULE, ORDER, OR OTHER PROCEEDING.—A civil action may be commenced under this paragraph, notwithstanding—

"(A) the existence of—

"(i) a decision by the Administrator under section 4A, 5(d)(3), or 6(c)(1); or

"(ii) a rule, testing consent agreement, or order under section 4, 5(d)(4), 6(d), or 6(h); or

"(B) the pendency of any administrative or judicial proceeding under any provision of this Act.";

(2) in subsection (d), by striking "section 6(a)" and inserting "section 6(c)"; and

(3) in subsection (f), in the first sentence, by striking "and unreasonable".

SEC. 10. INFORMATION COLLECTION AND REPORTING.

Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amended—

(1) in subsection (a)—

(A) in paragraph (3)(A)(ii)(I)—

(i) by striking "5(b)(4)" and inserting "5";

(ii) by inserting "section 4 or" after "in effect under"; and

(iii) by striking "5(e)," and inserting "5(d)(4);"; and

(B) by adding at the end the following:

"(4) RULES.—

"(A) DEADLINE.—

"(i) IN GENERAL.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall promulgate rules requiring the maintenance of records and the reporting of information known or reasonably ascertainable by the person making the report, including rules requiring processors to report information, so that the Administrator has the information necessary to carry out sections 4 and 6.

"(ii) MODIFICATION OF PRIOR RULES.—In carrying out this subparagraph, the Administrator may modify, as appropriate, rules promulgated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(B) CONTENTS.—The rules promulgated pursuant to subparagraph (A)—

"(i) may impose different reporting and recordkeeping requirements on

manufacturers and processors; and

"(ii) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported.

"(C) ADMINISTRATION.—In implementing the reporting and recordkeeping requirements under this paragraph, the Administrator shall take measures—

"(i) to limit the potential for duplication in reporting requirements;

"(ii) to minimize the impact of the rules on small manufacturers and processors; and

"(iii) to apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.

"(5) GUIDANCE.—The Administrator shall develop guidance relating to the information required to be reported under the rules promulgated under this subsection.";

(2) in subsection (b), by adding at the end the following:

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

"(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

"(I) cement, Portland, chemicals, CAS No. 65997–15–1;

"(II) cement, alumina, chemicals, CAS No. 65997–16–2;

"(III) glass, oxide, chemicals, CAS No. 65997–17–3;

"(IV) frits, chemicals, CAS No. 65997–18–4;

"(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

"(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature conventions, the Administrator shall—

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

"(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) RULES.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator, by rule, shall require manufacturers and processors to notify the Administrator, by not later than 180 days after the date of promulgation of the rule, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(ii) ACTIVE SUBSTANCES.—The Administrator shall, pursuant to paragraph (5)(A), designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—The rule promulgated by the Administrator pursuant to subparagraph (A) shall require—

"(i) the Administrator to maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

"(ii) a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

"(iii) the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C).

"(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are notified pursuant to subparagraph (A) or

identified as active substances under subsection (f)(1).

"(D) REQUIREMENTS OF REVIEW PLAN.—The review plan under subparagraph (C) shall—

"(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

"(ii) require the Administrator, in accordance with section 14—

"(I) to review each substantiation—

"(aa) submitted pursuant to clause (i) to determine if the claim warrants protection from disclosure; and

"(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

"(II) approve, modify, or deny each claim; and

"(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(iii) encourage manufacturers or processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

"(E) TIMELINE FOR COMPLETION OF REVIEWS.—

"(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

"(ii) CONSIDERATIONS.—

"(I) IN GENERAL.—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the

extension is necessary based on the number of applicable claims needing review and the available resources.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of reviews to be completed over the course of implementation of the plan.

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

"(A) IN GENERAL.—The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).

"(B) UPDATE.—The Administrator shall update the list of chemical substances designated as active substances as soon as practicable after the date of publication of the most recent data reported under—

"(i) part 711 of title 40, Code of Federal Regulations (or successor regulations); and

"(ii) the rules promulgated pursuant to subsection (a)(4).

"(C) CHANGE TO ACTIVE STATUS.—

"(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

"(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the inactive substance as confidential, the person shall—

"(I) in the notice submitted under clause (i), assert the claim; and

"(II) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

"(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

"(I) designate the applicable chemical substance as an active substance;

"(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific identity of the chemical substance and approve, modify, or deny the claim;

"(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of not less than 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator

shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines to be necessary.

"(D) CATEGORY STATUS.—The list of inactive substances shall not be considered to be a category for purposes of section 26(c).

"(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the rule required under this subsection, the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (or successor regulations), during the reporting period that most closely preceded the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as the interim list of active substances for the purposes of section 4A.

"(7) PUBLIC PARTICIPATION.—Subject to this subsection, the Administrator shall make available to the public—

"(A) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—

"(i) an active substance; or

"(ii) an inactive substance;

"(B) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received and approved by the Administrator pursuant to section 14; and

"(C) subject to section 14(g), the specific identity of any active substance for which—

"(i) no claim of protection against disclosure of the specific identity of the active substance pursuant to this subsection was received;

"(ii) a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or

"(iii) the time period for protection against disclosure of the specific identity of the active substance has expired.

"(8) LIMITATION.—No person may assert a new claim under this subsection for protection from disclosure of a specific identity of any active or inactive chemical substance for which a notice is received under paragraph (4)(A)(i) or (5)(C)(i) that is not on the confidential portion of the list published under paragraph (1).

"(9) CERTIFICATION.—Under the rule promulgated under this subsection, manufacturers and processors shall be required—

"(A) to certify that each report the manufacturer or processor submits complies with

the requirements of the rule, and that any confidentiality claims are true and correct; and

"(B) to retain a record supporting the certification for a period of 5 years beginning on the last day of the submission period.";

(3) in subsection (e)—

(A) by striking "Any person" and inserting the following:

"(1) IN GENERAL.—Any person"; and

(B) by adding at the end the following:

"(2) APPLICABILITY.—Any person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of harm to health and the environment."; and

(4) in subsection (f), by striking "For purposes of this section, the" and inserting the following: "In this section:

"(1) ACTIVE SUBSTANCE.—The term 'active substance' means a chemical substance—

"(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(B) that is added to the list published under subsection (b)(1) after that date of enactment; or

"(C) for which a notice is received under subsection (b)(5)(C).

"(2) INACTIVE SUBSTANCE.—The term 'inactive substance' means a chemical substance on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).

"(3) MANUFACTURE; PROCESS.—The".

SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.

Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the first sentence—

(i) by striking "presents or will present an unreasonable risk to health or the environment" and inserting "does not meet the safety standard"; and

(ii) by striking "such risk" the first place it appears and inserting "the risk posed by the substance or mixture";

(B) in paragraph (2), in the matter following subparagraph (B), by striking "section 6 or 7" and inserting "section 6(d) or section 7"; and

(C) in paragraph (3), by striking "section 6 or 7" and inserting "section 6(d) or 7";

(2) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare"

and inserting "Health and Human Services"; and

(3) by adding at the end the following:

"(e) Exposure Information.—If the Administrator obtains information related to exposures or releases of a chemical substance that may be prevented or reduced under another Federal law, including laws not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.".

SEC. 12. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA.

Section 10 of the Toxic Substances Control Act (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".

SEC. 13. EXPORTS.

Section 12 of the Toxic Substances Control Act (15 U.S.C. 2611) is amended—

(1) in subsection (a), by striking paragraph (2) and inserting the following:

"(2) EXCEPTION.—Paragraph (1) shall not apply to any chemical substance that the Administrator determines—

"(A) under section 5 is not likely to meet the safety standard; or

"(B) under section 6 does not meet the safety standard.

"(3) WAIVERS.—For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—

"(A) determine that paragraph (1) shall not apply to the mixture or article; or

"(B) establish a threshold concentration in a mixture or article at which paragraph (1) shall not apply.

"(4) TESTING.—The Administrator may require testing under section 4 of any chemical substance or mixture exempted from this Act under paragraph (1) for the purpose of determining whether the chemical substance or mixture meets the safety standard within the United States.";

(2) by striking subsection (b) and inserting the following:

"(b) Notice.—

"(1) IN GENERAL.—A person shall notify the Administrator that the person is exporting or intends to export to a foreign country—

"(A) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 5 is not likely to meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(B) a chemical substance or a mixture containing a chemical substance that the

Administrator has determined under section 6 does not meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(C) a chemical substance for which the United States is obligated by treaty to provide export notification;

"(D) a chemical substance or mixture subject to a prohibition or other restriction pursuant to a rule, order, or consent agreement in effect under this Act; or

"(E) a chemical substance or mixture for which the submission of information is required under section 4.

"(2) RULES.—

"(A) IN GENERAL.—The Administrator shall promulgate rules to carry out paragraph (1).

"(B) CONTENTS.—The rules promulgated pursuant to subparagraph (A) shall—

"(i) include such exemptions as the Administrator determines to be appropriate, which may include exemptions identified under section 5(h); and

"(ii) indicate whether, or to what extent, the rules apply to articles containing a chemical substance or mixture described in paragraph (1).

"(3) NOTIFICATION.—The Administrator shall submit to the government of each country to which a chemical substance or mixture is exported—

"(A) for a chemical substance or mixture described in subparagraph (A), (B), or (D) of paragraph (1), a notice of the determination, rule, order, consent agreement, requirement, or designation;

"(B) for a chemical substance described in paragraph (1)(C), a notice that satisfies the obligation of the United States under the applicable treaty; and

"(C) for a chemical substance or mixture described in paragraph (1)(E), a notice of availability of the information on the chemical substance or mixture submitted to the Administrator."; and

(3) in subsection (c)—

(A) by striking paragraph (3); and

(B) by redesignating paragraphs (4) through (6) as paragraphs (3) through (5), respectively.

~~SEC. 14. IMPORTS.~~

~~Section 13 of the Toxic Substances Control Act (15 U.S.C. 2612) is amended to read as follows:~~

~~"SEC. 13. IMPORTS.~~

~~"(a) Refusal of Entry.—~~

~~"(1) IN GENERAL.—The Secretary of Homeland Security shall refuse entry into the~~

Commented [S18]: Propose deleting imports section and returning to current law to address concern over "articles" roll-back from current law.

customs territory of the United States (as defined in general note 2 to the Harmonized Tariff Schedule of the United States) any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry, if—

"(A) the Administrator—

"(i) has determined under section 6(e) that the chemical substance or mixture does not meet the safety standard; and

"(ii) has promulgated a rule pursuant to section 6(d) banning the chemical substance or mixture, as of the effective date of the rule;

"(B) the chemical substance—

"(i) is not included on the list under section 8(b)(1); and

"(ii) is not exempt from any requirement to be included on that list by this title or a rule promulgated by the Administrator pursuant to this title; or

"(C) the chemical substance, mixture, or any article containing the chemical substance or mixture is offered for entry in violation of—

"(i) a rule, consent agreement, or order in effect under this Act; or

"(ii) an order issued in a civil action brought under section 7 or title IV.

"(2) PROCEDURE.—

"(A) IN GENERAL.—Subject to subparagraph (B), if a chemical substance, mixture, or article containing a chemical substance or mixture is refused entry under paragraph (1), the Secretary of Homeland Security—

"(i) shall notify the consignee of the entry of the refusal;

"(ii) shall not release the chemical substance or mixture to the consignee; and

"(iii) shall cause the disposal or storage of the chemical substance or mixture under such rules as the Secretary may prescribe, if the chemical substance or mixture has not been exported by the consignee during the 90-day period beginning on the date of receipt of the notice of the refused entry.

"(B) EXCEPTION.—

"(i) IN GENERAL.—The Secretary of Homeland Security, pending a review by the Administrator, may release to the consignee the chemical substance or mixture if the consignee—

"(I) executes a bond for the amount of the full invoice of the chemical substance or mixture (as set forth in the customs entry); and

"(II) pays a duty on the chemical substance or mixture.

"(ii) ADMINISTRATION.—If a consignee fails to return a chemical substance or mixture released to that consignee under clause (i) for any cause to the custody of the Secretary of Homeland Security on demand, the consignee shall be liable to the United States for liquidated damages equal to the full amount of the bond executed under clause (i)(I).

"(C) STORAGE.—All charges for storage, cartage, and labor on or for the disposal of a chemical substance or mixture that is refused entry or released under this subsection shall be paid by the owner or consignee, and a default on that payment shall constitute a lien against any future entry made by the owner or consignee.

"(b) Certification.—

"(1) IN GENERAL.—A person offering a chemical substance or mixture subject to this Act for entry into the customs territory of the United States shall certify to the Secretary of Homeland Security that—

"(A) after reasonable inquiry and to the best knowledge and belief of the person, the chemical substance or mixture is in compliance with any applicable rule, consent agreement, or order under section 5 or 6; and

"(B) the chemical substance—

"(i) is included on the list under section 8(b)(1); or

"(ii) is exempt from any requirement to be included on that list by this title or a rule promulgated by the Administrator pursuant to this title.

"(2) ARTICLES.—

"(A) IN GENERAL.—The Administrator, by rule, may require certification under paragraph (1) for an article containing a chemical substance or mixture that is subject to rule under section 5 or 6.

"(B) REQUIREMENT.—The rule under subparagraph (A) shall identify, with reasonable specificity, the types of articles, including parts or components of articles, that will be subject to the certification requirement.

"(C) FACTORS FOR CONSIDERATION.—In determining the need for and content of a certification rule under this paragraph, the Administrator shall take into consideration—

"(i) the utility of the certification to enforcement of the applicable rule, consent agreement, or order under section 5 or 6;

"(ii) whether to limit the contribution of imported articles to the potential risk presented by exposure to the chemical substance or mixture subject to rule under section 5 or 6;

"(iii) the impact on commerce and potential for the certification to impede or disrupt import of articles;

"(iv) the frequency or duration of the certification requirement; and

"(v) specification of"(iii) whether to specify the concentration of a chemical substance in an article that would subject the article to the certification requirement.

"(3) Reasonable inquiry.—

"(A) In general.—For purposes of a certification under paragraph (1), reasonable inquiry shall include good faith reliance by an importer on—

"(i) a safety data sheet or similar declaration provided by a supplier that documents the specific identity of the chemical substance or the specific identities of all chemical substances in a mixture; or

"(ii) for chemical substances or mixtures claimed by the supplier as confidential, or not otherwise disclosed by the supplier, a certification by the supplier that the imported chemical substance or mixture satisfies the applicable certification requirements under paragraph (1).

"(B) Articles.—For purposes of a certification under paragraph (2), reasonable inquiry shall include good faith reliance by an importer on a certification by the supplier that the imported article satisfies the applicable certification requirements in a rule promulgated pursuant to paragraph (2).

"(4) INFORMATION REGARDING IDENTITY.—For purposes of this subsection, the Administrator shall provide publicly accessible information regarding the identity of a chemical substance or mixture subject to rule under this Act that would be readily understood in import transactions.

"(c) Notice.—A person offering a chemical substance for entry into the customs territory of the United States shall notify the Secretary of Homeland Security if—

"(1) the chemical substance or chemical substance in a mixture is a high priority substance;

"(2) the chemical substance or chemical substance in a mixture is 1 for which the United States is obligated to provide export notification by treaty; or

"(3) the chemical substance or chemical substance in a mixture—

"(A) is the subject of a safety assessment and safety determination conducted pursuant to section 6; and

"(B) has been found not to meet the safety standard.

"(d) Rules.—

"(1) IN GENERAL.—The Secretary of Homeland Security, after consultation with the Administrator, shall promulgate rules to carry out this section.

"(2) APPLICATION.—The rules under paragraph (1) may modify the application of any requirement of this section, as appropriate for the efficient and effective implementation of this Act.".

SEC. 15. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer and specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

"(7) Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if—

"(A) the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5; and

"(B) the claim—

"(i) is not subject to an exception under subsection (e); or

"(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (f)(2) or (g).

"(c) Information Not Protected From Disclosure.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

"(1) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

"(A) IN GENERAL.—Subject to subparagraph (B), subsection (a) does not prohibit the disclosure of—

"(i) any health and safety study that is submitted under this Act with respect to—

"(I) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

"(II) any chemical substance or mixture for which—

"(aa) testing is required under section 4; or

"(bb) a notification is required under section 5; or

"(ii) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in subclause (I) or (II) of clause (i).

"(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph authorizes the release of any information that discloses—

"(i) a process used in the manufacturing or processing of a chemical substance or mixture; or

"(ii) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

"(2) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(3) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

"(A) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

"(B) A safety assessment developed, or a safety determination made, under section 6.

"(C) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

"(D) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

"(4) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is otherwise eligible for protection under this section and contained in a submission of information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

"(3) BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance—

"(A) subject to sub section (g)(2) and (3), information relating to such chemical substance that has been protected from disclosure shall be disclosed unless the Administrator determines that disclosure of such information is not in the public interest;

"(B) the Administrator shall determine what portion of that information, if any, should remain protected from disclosure; and

"(C) the Administrator shall make public the information that the Administrator has determined is not to be protected from disclosure.

Commented [S19]: Suggested replacement.

~~"(5) BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance—~~

~~"(A) any protection from disclosure provided under this section with respect to information relating to the chemical substance shall no longer apply; and~~

~~"(B) the Administrator promptly shall make the information public.~~

"(d) Requirements for Confidentiality Claims.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name shall—

"(i) conform with guidance prescribed by the Administrator under paragraph (3)(A); and

"(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are considered to be confidential; and

"(II) the disclosure of which would be likely to harm the competitive position of the person.

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in paragraphs (1) through (7) of subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the information that has been submitted is true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a) shall be disclosed if—

"(1) the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) the Administrator determines that disclosure is necessary to protect health or the environment;

"(4) the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, if—

"(A) 1 or more applicable agreements with the Administrator that conform with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the

Administrator to safeguard the information; and

"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;

"(5) a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement shall conform with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the

treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

"(9) the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION PROTECTED FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information that meets the requirements of subsection (d) for a period of 10 years, unless, prior to the expiration of the period—

"(i) an affected person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in subsection (g)(2).

"(B) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph (A), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph (A), a person reasserting the relevant claim shall submit to the Administrator a statement substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—

"(aa) review the request;

"(bb) make a determination regarding whether the information for which the request is made continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of not more than 10 years; or

"(BB) deny the claim.

"(C) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph (B), if the Administrator determines that the relevant statement under subparagraph (B)(ii)(I)—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection against disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating rules pursuant to section 6(d), subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d).

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection from disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) as necessary to comply with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(ii) if information available to the Administrator provides a basis that the

requirements of section 552(b)(4) of title 5, United States Code, are no longer met; or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator on expiration of the period for appeal under subsection (g)(3), that has expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

"(B) DENIAL OR MODIFICATION.—

"(i) IN GENERAL.—Except as provided in subsections (c) and (f), the Administrator shall deny a claim to protect a chemical identity from disclosure

only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).

"(ii) REASONS FOR DENIAL OR MODIFICATION.—The Administrator shall provide to a person that has submitted a claim described in clause (i) a written statement of the reasons for the denial or modification of the claim.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection (b)(7), review all claims under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim under paragraph (1), the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

"(B) RELEASE OF INFORMATION.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

"(ii) EXCEPTIONS.—

"(I) IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

"(II) NO NOTIFICATION.—For information under paragraph (1), (2), (6), (7), or (9) of subsection (e), no prior notification shall be necessary.

"(3) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(4) ADMINISTRATION.—In carrying out this subsection, the Administrator shall use the procedures described in part 2 of title 40, Code of Federal Regulations (or successor regulations).

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information submitted to the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

"(2) PRIOR ACTIONS.—Nothing in this Act prevents the Administrator from reviewing,

requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

SEC. 16. PROHIBITED ACTS.

Section 15 of the Toxic Substances Control Act (15 U.S.C. 2614) is amended by striking paragraph (1) and inserting the following:

"(1) fail or refuse to comply with—

"(A) **any requirement under section 4(c)(4);**

Commented [S20]: Not OK to penalize for a failure to use non-animal tests in voluntary testing.

"(B) any rule promulgated, consent agreement entered into, or order issued under section 4;

~~"(B)~~**"(C)** any requirement under section 5 or 6;

~~"(C)~~**"(D)** any rule promulgated, consent agreement entered into, or order issued under section 5 or 6; or

~~"(D)~~**"(E)** any requirement of, or any rule promulgated or order issued pursuant to title II;".

SEC. 17. PENALTIES.

Section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) is amended—

(1) in subsection (a)(1)—

(A) in the first sentence—

(i) by inserting "this Act or a rule or order promulgated or issued pursuant to this Act, including" after "a provision of"; and

(ii) by striking "$25,000" and inserting "$37,500"; and

(B) in the second sentence, by striking" violation of section 15 or 409" and inserting "violation of this Act"; and

(2) in subsection (b)—

(A) by striking "Any person who" and inserting the following:

"(1) IN GENERAL.—Any person that";

(B) by striking "section 15 or 409" and inserting "this Act";

(C) by striking "$25,000" and inserting "$50,000"; and

(D) by adding at the end the following:

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of this Act, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be subject on

conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

"(B) ORGANIZATIONS.—An organization that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation.

"(3) KNOWLEDGE OF IMMINENT DANGER OR INJURY.—For purposes of determining whether a defendant knew that the violation placed another individual in imminent danger of death or serious bodily injury—

"(A) the defendant shall be responsible only for actual awareness or actual belief possessed; and

"(B) knowledge possessed by an individual may not be attributed to the defendant.".

SEC. 18. STATE-FEDERAL RELATIONSHIP.

Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following:

"(a) In General.—

"(1) ESTABLISHMENT OR ENFORCEMENT.—Except as provided in subsections **(b),** (c), (d), (e), **and** (f), ~~and (g),~~ and subject to paragraph (2), no State or political subdivision of a State may establish or continue to enforce any of the following:

Commented [S21]: Conforming change not OK.

"(A) TESTING AND INFORMATION COLLECTION.—A statute or administrative action to require the development of information on a chemical substance or category of substances that is reasonably likely to produce the same information required under section 4, 5, or 6 in—

"(i) a rule promulgated by the Administrator;

"(ii) a testing consent agreement entered into by the Administrator; or

"(iii) an order issued by the Administrator.

"(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

"(i) found to meet the safety standard and consistent with the scope of the determination made under section 6; or

"(ii) found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

"(C) SIGNIFICANT NEW USE.—A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(2) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of State statutes and administrative actions applicable to specific substances shall not occur

until the effective date of the applicable action described in paragraph (1) taken by the Administrator.

~~"(b) New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions.—Except as provided in subsections (c), (d), and (e), no State or political subdivision of a State may establish (after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) a statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance designated under section 4A, as of the date on which the Administrator commences a safety assessment under section 6.~~

"(b) New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions.—Except as provided in subsections (c), (d), and (e), no State or political subdivision of a State may establish a statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance designated under section 4A, as of the date on which the Administrator commences a safety assessment under section 6. This section shall not be construed to restrict the enforcement of any state statute or administrative action taken prior to the date the Administrator commences a safety assessment under section 6

Commented [S22]: Not OK to delete. Restore, but ok to add/clarify that enforcement of actions can continue. Example: *"This section shall not be construed to restrict the enforcement of any state statute or administrative action taken prior to the date the Administrator commences a safety assessment under section 6."*

And OK to delete: *(after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act)* to help with clarification.

"~~(c)~~ Scope of Preemption.—Federal preemption under ~~subsections~~ **subsection** (a) ~~and (b)~~ of State statutes and administrative actions applicable to specific substances shall apply only to—

Commented [S23]: Conforming change not OK.

"(1) the chemical substances or category of substances subject to a rule, order, or consent agreement under section 4;

"(2) the uses or conditions of use of such substances that are identified by the Administrator as subject to review in a safety assessment and included in the scope of the safety determination made by the Administrator for the substance, or of any rule the Administrator promulgates pursuant to section 6(d); or

"(3) the uses of such substances that the Administrator has specified as significant new uses and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"~~(d)~~**(c)** Exceptions.—

"(1) IN ~~GENERAL.—SUBSECTIONS (A) AND (B)~~ GENERAL.—**Subsection (a)** shall not apply to a statute or administrative action of a State or a political subdivision of a State applicable to a specific chemical substance that—

"(A) is adopted **or authorized** under the authority of~~, or authorized to comply with,~~ **any other Federal law or adopted for the purpose of satisfying or obtaining authorization or approval under** any other Federal law;

"(B) implements a reporting, monitoring, or other information collection obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law; ~~or~~

"(C) is adopted pursuant to authority under a law of the State or political subdivision

of the State related to water quality, air quality, or waste treatment or disposal, ~~unless the action taken by the State or political subdivision of a State—~~ **except to the extent that the action—**

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii)(I) **addresses the same hazards and exposures, with respect to the same conditions of use, as** ~~is already required by a decision by the Administrator under section 5 or 6;~~

~~"(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that~~ are included in the scope of a safety determination pursuant to section 6 ~~or the scope of a significant new use rule promulgated pursuant to section 5~~, but is inconsistent with the action of the Administrator; or

"(III)**"(II)** would cause a violation of the applicable action by the Administrator under section 5 or 6**; or**

"(D) is identical to a requirement prescribed by the Administrator.~~-~~

Commented [S24]: Propose deleting this section from lines XX through XX. This is covered in section (d)(2) below.

"(2) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—Nothing in this Act, nor any amendment made by this Act, nor any rule, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

"(A) is adopted **or authorized** under the authority of~~, or authorized to comply with,~~ **any other Federal law or adopted for the purpose of satisfying or obtaining authorization or approval under** any other Federal law;

Commented [S25]: Waiting for EPA T.A. on this. Not accepted yet.

"(B) implements a reporting, monitoring, disclosure, or other information collection obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law; ~~or~~

Commented [S26]: Suggest adding to ensure "disclosure" laws are protected.

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, ~~unless the action taken by the State or political subdivision of a State—~~ **except to the extent that the action—**

Commented [S27]: OK

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii)(I) **addresses the same hazards and exposures, with respect to the same conditions of use as** ~~is already required by a decision by the Administrator under section 5 or 6;~~

Commented [S28]: OK

~~"(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that~~ are included in the scope of a safety determination

pursuant to section 6 ~~or the scope of a significant new use rule promulgated pursuant to section 5~~, but is inconsistent with the action of the Administrator; or

~~"(III)~~**"(II)** would cause a violation of the applicable action by the Administrator under section 5 or 6**; or**

"(D) is identical to a requirement prescribed by the Administrator. Upon request of the Administrator, a State shall demonstrate that the enforcement of the State statute or administrative action is equivalent to, no more stringent than, and consistent with federal enforcement of the applicable federal requirement. This paragraph does not authorize the imposition of State penalties that duplicate penalties assessed for violations of federal law.

"(3) APPLICABILITY TO CERTAIN RULES OR ORDERS.—Notwithstanding subsection ~~(e)~~**(d)**—

"(A) nothing in this section shall be construed as modifying the effect under this section, as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, of any rule or order promulgated or issued under this Act prior to that effective date; and

"(B) with respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 6 prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act with regards to manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance, this section (as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after that effective date, unless the latter rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under subsection (b) or (c) of section 4A or as an additional priority for safety assessment and safety determination under section 4A(d).

~~"(e)~~**"(d)** Preservation of Certain State Law.—

"(1) IN GENERAL.—Nothing in this Act, subject to subsection ~~(g)~~**(f)** of this section, shall—

"(A) be construed to preempt or otherwise affect the authority of a State or political subdivision of a State to continue to enforce any action taken before ~~January~~ August 1, 2015, under the authority of a State law that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance; ~~or~~

"(B) be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003**; or**

"(C) be construed to preempt any law enacted before August 1, 2015, and any

Commented [S29]: OK

Commented [S30]: OK with proposed modification.

Commented [S31]: Suggested addition to clarify that States can continue to enforce restrictions that were put in place before August 1, 2015.

Commented [S32]: See below.

subsequent action taken under the authority of that State law, that requires disclosure and restricts the use of a finite list of chemical substances in children's products.

"(2) EFFECT OF SUBSECTION.—This subsection does not affect, modify, or alter the relationship between State and Federal law pursuant to any other Federal law.

~~"(f)~~**"(e)** State Waivers.—

"(1) IN GENERAL.—Upon application of a State or political subdivision of a State, the Administrator **may** ~~may—~~

~~"(A)~~ by rule, exempt from subsection (a), under such conditions as may be prescribed in the rule, a statute or administrative action of that State or political subdivision of the State that relates to the effects of, or exposure to, a chemical substance under the conditions of use if the Administrator determines that—

~~"(i)~~**"(A)** compelling State or local conditions warrant granting the waiver to protect health or the environment;

~~"(ii)~~**"(B)** compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

~~"(iii)~~**"(C)** compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

~~"(iv)~~**"(D)** based on the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is consistent with sound objective scientific practices, the weight of the evidence, and the best available science; or

~~"(B) exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—~~

~~"(i) the State has a compelling local interest that warrants granting the waiver to protect health or the environment;~~

~~"(ii) compliance with the proposed requirement of the State will not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;~~

~~"(iii) compliance with the proposed requirement would not cause a violation of any applicable Federal law, rule, or order; and~~

~~"(iv) the proposed requirement is grounded in reasonable scientific concern.~~

"(2) APPROVAL OF A STATE WAIVER REQUEST.—The Administrator shall grant or deny a waiver **application** ~~application—~~

~~"(A)~~ not later than 180 days after the date on which an application under paragraph (1)~~(A) is submitted; and~~

Commented [S33]: Not OK. Savings clause above modified for August 1st date. This clause grandfathers in future (subsequent) restrictions taken under that law. There are also concerns about what is the "finite" list. Therefore, we recommend changing the date to August 1st, 2015 in the clause above.

Commented [S34]: Suggest removing "local" to make the waiver easier.

Formatted: Highlight

Formatted: Highlight

Commented [S35]: Not OK to delete.

~~"(B) not later than 90 days after the date on which an application under paragraph (1)(B) is submitted.~~

"(3) NOTICE AND COMMENT.—The application of a State or political subdivision of the State shall be subject to public notice and comment.

"(4) FINAL AGENCY ACTION.—The decision of the Administrator on the application of a State or political subdivision of the State shall be—

"(A) considered to be a final agency action; and

"(B) subject to judicial review.

~~"(5) Duration of waivers.—A waiver granted under paragraph (1)(B) shall remain in effect until the later of—~~

~~"(A) such time as the safety assessment and safety determination is completed; and~~

~~"(B) the date on which compliance with an applicable rule issued under section 6(d) is required.~~

~~"(6)~~ JUDICIAL REVIEW OF WAIVERS.—Not later than 60 days after the date on which the Administrator makes a determination on an application of a State or political subdivision of the State under ~~subparagraph (A) or (B) of~~ paragraph (1), any person may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.

~~(7) Presumption of Approval.—If the Administrator fails to meet the deadlines under section 6(a), the application of a State or political subdivision of a State under paragraph (1)(B) shall be presumed to be approved. Notwithstanding paragraph (4), approval of a waiver application under this paragraph shall not be considered final agency action or be subject to judicial review.~~

"(6) JUDICIAL REVIEW OF LOW-PRIORITY DECISIONS.—

"(A) IN GENERAL.—Not later than 60 days after the Administrator makes a designation under section 4A(b)(4), any person may commence a civil action to challenge the designation. **Any person may commence a civil action to challenge the designation by the Administrator of** ~~"(7) Judicial review of prioritization screening decision.—Not later than 60 days after the date on which the Administrator makes a decision on a recommendation made under section 4A(b)(4) to designate~~ a chemical substance as a low ~~priority, the Governor of a State or a State agency with responsibility for protecting health and the environment that submitted the recommendation under section 4A(a)(4)(A), as applicable, may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which~~**-priority substance under section 4A(b)(4).**

"(B) JURISDICTION.—The United States Court of Appeals for the District of Columbia circuit ~~district courts~~ shall have exclusive jurisdiction over ~~the determination.~~ **a civil action filed under this paragraph.**

~~"(g)~~**"(f)** Savings.—

Commented [S36]: Conforming edit not OK.

Commented [S37]: Conforming edit not OK.

Commented [S38]: Conforming edit not OK

Commented [S39]: Suggest adding this language to address concern with High-Priority Preemption. This would allow States to begin a new prohibition on a high-priority chemical if EPA misses any deadlines.

Commented [S40]: Not OK.

Commented [S41]: Not ok. U.S. Court of Appeals for the District of Columbia Circuit ok.

"(1) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF OR CRIMINAL CONDUCT.—

"(A) IN GENERAL.—Nothing in this Act, nor any amendment made by this Act, nor any safety standard, rule, requirement, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall be construed to preempt, displace, or supplant any state or Federal common law rights or any state or Federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.

"(B) CLARIFICATION OF NO PREEMPTION.—Notwithstanding any other provision of this Act, nothing in this Act, nor any amendments made by this Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any State law, maritime law, or Federal common law or statutory theory.

"(2) NO EFFECT ON PRIVATE REMEDIES.—

"(A) ~~NOTHING~~ **IN GENERAL.—Nothing** in this Act, nor any amendments made by this Act, nor any rules, regulations, requirements, safety assessments, safety determinations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.

Commented [S42]: OK

"(B) ~~THIS~~ **AUTHORITY OF COURTS.—This** Act does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, safety assessments, scientific assessments, or orders issued pursuant to this Act.".

Commented [S43]: OK

SEC. 19. JUDICIAL REVIEW.

Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking "section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting "section 4(a), 5(d), 6(c), 6(d), 6(g), or 8, or title II or IV"; and

(ii) in subparagraph (B), by striking "an order issued under subparagraph (A) or (B) of section 6(b)(1)" and inserting "an order issued under this title"; and

(B) in paragraph (2), in the first sentence, by striking "paragraph (1)(A)" and inserting "paragraph (1)"; and

(C) by striking paragraph (3); and

(2) in subsection (c)(1)(B)—

(A) in clause (i)—

(i) by striking "section 4(a), 5(b)(4), 6(a), or 6(e)" and inserting "section 4(a), 5(d), 6(d), or 6(g)"; and

(ii) by striking "evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;" and inserting "evidence (including any matter) in the rulemaking record, taken as a whole; and"; and

(B) by striking clauses (ii) and (iii) and the matter following clause (iii) and inserting the following:

"(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule, except as part of the rulemaking record, taken as a whole.".

SEC. 20. CITIZENS' PETITIONS.

Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an order under section 4 or 5(d)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "an order under section 4 or 5(d)"; and

(B) in paragraph (4), by striking subparagraph (B) and inserting the following:

"(B) DE NOVO PROCEEDING.—

"(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to promulgate a rule pursuant to section 4, 5, 6, or 8 or an order issued under section 4 or 5, the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.

"(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a rule or order under section 4, the information available to the Administrator is insufficient for the Administrator to perform an action described in section 4, 4A, 5, or 6(d);

"(bb) in the case of a petition to issue an order under section 5(d), there is a reasonable basis to conclude that the chemical substance is not likely to meet the safety standard;

"(cc) in the case of a petition to initiate a proceeding for the issuance of a rule under section 6(d), there is a reasonable basis to conclude that the chemical substance will not meet the safety standard; or

"(dd) in the case of a petition to initiate a proceeding for the issuance of a rule under section 8, there is a reasonable basis to conclude that the rule is necessary to protect health or the environment or ensure that the chemical substance meets the safety standard.

"(II) DEFERMENT.—The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

"(aa) the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act; and

"(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.".

SEC. 21. EMPLOYMENT EFFECTS.

Section 24(b)(2)(B)(ii) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by striking "section 6(c)(3)," and inserting "the applicable requirements of this Act;".

SEC. 22. STUDIES.

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.

SEC. 23. ADMINISTRATION.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) by striking subsection (b) and inserting the following:

"(b) Fees.—

"(1) IN GENERAL.—The Administrator shall establish, not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, by rule—

"(A) the payment of 1 or more reasonable fees as a condition of submitting a notice or requesting an exemption under section 5;

"(B) the payment of 1 or more reasonable fees by a manufacturer or processor that—

"(i) is required to submit a notice pursuant to the rule promulgated under section 8(b)(4)(A)(i) identifying a chemical substance as active;

"(ii) is required to submit a notice pursuant to section 8(b)(5)(B)(i) changing the status of a chemical substance from inactive to active;

"(iii) is required to report information pursuant to the rules promulgated under section 8(a)(4); and

"(iv) manufactures or processes a chemical substance subject to a safety assessment and safety determination pursuant to section 6.

"(2) UTILIZATION AND COLLECTION OF FEES.—The Administrator shall—

"(A) utilize the fees collected under paragraph (1) only to defray costs associated with the actions of the Administrator—

"(i) to collect, process, review, provide access to, and protect from disclosure (where appropriate) information on chemical substances under this Act;

"(ii) to review notices and make determinations for chemical substances under paragraphs (1) and (3) of section 5(d) and impose any necessary restrictions under section 5(d)(4);

"(iii) to make prioritization decisions under section 4A;

"(iv) to conduct and complete safety assessments and determinations under section 6; and

"(v) to conduct any necessary rulemaking pursuant to section 6(d);

"(B) insofar as possible, collect the fees described in paragraph (1) in advance of conducting any fee-supported activity;

"(C) deposit the fees in the Fund established by paragraph (4)(A); and

"(D) not collect excess fees or retain a significant amount of unused fees.

"(3) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—In setting fees under this section, the Administrator shall—

"(A) take into account the cost to the Administrator of conducting the activities described in paragraph (2);

"(B) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

"(C) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to defray approximately 25 percent of the costs of conducting the activities identified in paragraph (2)(A), not to exceed $18,000,000, not including fees under subparagraph (E) of this paragraph;

"(D) reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

"(E) for substances designated as additional priorities pursuant to section 4A(c), establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the safety assessment and safety determination under section 6;

"(F) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) or subchapter III of chapter 5 of title 5, United States Code, is applicable with respect to such meetings;

"(G) beginning with the fiscal year that is 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 3 years

thereafter, after consultation with parties potentially subject to the fees and their representatives, increase or decrease the fees established under paragraph (1) as necessary—

"(i) to ensure that funds deposited in the Fund are sufficient to conduct the activities identified in paragraph (2)(A) and the full costs of safety assessments and safety determinations pursuant to subparagraph (E); and

"(ii) to account for inflation;

"(H) adjust fees established under paragraph (1) as necessary to vary on account of differing circumstances, including reduced fees or waivers in appropriate circumstances, to reduce the burden on manufacturing or processing, remove barriers to innovation, or where the costs to the Administrator of collecting the fees exceed the fee revenue anticipated to be collected; and

"(I) if a notice submitted under section 5 is refused or subsequently withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

"(4) TSCA IMPLEMENTATION FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the 'TSCA Implementation Fund' (referred to in this subsection as the 'Fund'), consisting of—

"(i) such amounts as are deposited in the Fund under paragraph (2)(C); and

"(ii) any interest earned on the investment of amounts in the Fund; and

"(iii) any proceeds from the sale or redemption of investments held in the Fund.

"(B) CREDITING AND AVAILABILITY OF FEES.—

"(i) IN GENERAL.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation.

"(ii) REQUIREMENTS.—Fees collected under this section shall not—

"(I) be made available or obligated for any purpose other than to defray the costs of conducting the activities identified in paragraph (2)(A);

"(II) otherwise be available for any purpose other than implementation of this Act; and

"(III) so long as amounts in the Fund remain available, be subject to restrictions on expenditures applicable to the Federal government as a whole.

"(C) UNUSED FUNDS.—Amounts in the Fund not currently needed to carry out this subsection shall be—

"(i) maintained readily available or on deposit;

"(ii) invested in obligations of the United States or guaranteed by the United States; or

"(iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

"(D) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2015) of the Office of Pollution Prevention and Toxics of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for covered functions for fiscal year 2015 (excluding the amount of any fees appropriated for the fiscal year).

"(5) AUDITING.—

"(A) FINANCIAL STATEMENTS OF AGENCIES.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of an executive agency.

"(B) COMPONENTS.—The annual audit required under sections 3515(b) and 3521 of that title of the financial statements of activities under this subsection shall include an analysis of—

"(i) the fees collected under paragraph (1) and disbursed;

"(ii) compliance with the deadlines established in section 6 of this Act;

"(iii) the amounts budgeted, appropriated, collected from fees, and disbursed to meet the requirements of sections 4, 4A, 5, 6, 8, and 14, including the allocation of full time equivalent employees to each such section or activity; and

"(iv) the reasonableness of the allocation of the overhead associated with the conduct of the activities described in paragraph (2)(A).

"(C) INSPECTOR GENERAL.—The Inspector General of the Environmental Protection Agency shall—

"(i) conduct the annual audit required under this subsection; and

"(ii) report the findings and recommendations of the audit to the Administrator and to the appropriate committees of Congress.

"(6) TERMINATION.—The authority provided by this section shall terminate at the conclusion of the fiscal year that is 10 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, unless otherwise reauthorized or modified by Congress.";

(2) in subsection (e), by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services"; and

(3) adding at the end the following:

"(h) Prior Actions.—Nothing in this Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

SEC. 24. DEVELOPMENT AND EVALUATION OF TEST

METHODS AND SUSTAINABLE CHEMISTRY.

Section 27 of the Toxic Substances Control Act (15 U.S.C. 2626) is amended—

(1) in subsection (a), in the first sentence by striking "Health, Education, and Welfare" and inserting "Health and Human Services"; and

(2) by adding at the end the following:

"(c) Sustainable Chemistry Program.—The President shall establish an interagency Sustainable Chemistry Program to promote and coordinate Federal sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities.

"(d) Program Activities.—The activities of the Program shall be designed to—

"(1) provide sustained support for sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training through—

"(A) coordination of sustainable chemistry research, development, demonstration, and technology transfer conducted at Federal laboratories and agencies; and

"(B) to the extent practicable, encouragement of consideration of sustainable chemistry in, as appropriate—

"(i) the conduct of Federal and State science and engineering research and development; and

"(ii) the solicitation and evaluation of applicable proposals for science and engineering research and development;

"(2) examine methods by which the Federal Government can create incentives for consideration and use of sustainable chemistry processes and products, including innovative financing mechanisms;

"(3) expand the education and training of undergraduate and graduate students and professional scientists and engineers, including through partnerships with industry, in sustainable chemistry science and engineering;

"(4) collect and disseminate information on sustainable chemistry research, development, and technology transfer including information on—

"(A) incentives and impediments to development, manufacturing, and commercialization;

"(B) accomplishments;

"(C) best practices; and

"(D) costs and benefits;

"(5) support (including through technical assistance, participation, financial support, or other forms of support) economic, legal, and other appropriate social science research to identify barriers to commercialization and methods to advance commercialization of sustainable chemistry.

"(e) Interagency Working Group.—

"(1) ESTABLISHMENT.—Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the President, in consultation with the Office of Science and Technology Policy, shall establish an Interagency Working Group that shall include representatives from the National Science Foundation, the National Institute of Standards and Technology, the Department of Energy, the Environmental Protection Agency, the Department of Agriculture, the Department of Defense, the National Institutes of Health, and any other agency that the President may designate to oversee the planning, management, and coordination of the Program.

"(2) GOVERNANCE.—The Director of the National Science Foundation and the Assistant Administrator for Research and Development of the Environmental Protection Agency, or their designees, shall serve as co-chairs of the Interagency Working Group.

"(3) RESPONSIBILITIES.—In overseeing the planning, management, and coordination of the Program, the Interagency Working Group shall—

"(A) establish goals and priorities for the Program, in consultation with the Advisory Council;

"(B) provide for interagency coordination, including budget coordination, of activities under the Program;

"(C) meet not later than 90 days from its establishment and periodically thereafter; and

"(D) establish and consult with an Advisory Council on a regular basis.

"(4) MEMBERSHIP.—The Advisory Council members shall not be employees of the Federal Government and shall include a diverse representation of knowledgeable individuals from the private sector (including small- and medium-sized enterprises from across the value chain), academia, State and tribal governments, and nongovernmental organizations and others who are in a position to provide expertise.

"(f) Agency Budget Requests.—

"(1) IN GENERAL.—Each Federal agency and department participating in the Program shall, as part of its annual request for appropriations to the Office of Management and Budget, submit a report to the Office of Management and Budget that—

"(A) identifies the activities of the agency or department that contribute directly to the Program; and

"(B) states the portion of the agency or department's request for appropriations that is allocated to those activities.

"(2) ANNUAL BUDGET REQUEST TO CONGRESS.—The President shall include in the annual budget request to Congress a statement of the portion of the annual budget request for each agency or department that will be allocated to activities undertaken pursuant to the Program.

"(g) Report to Congress.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Interagency Working Group shall submit a report to the Committee on Science, Space, and Technology and Committee on

Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works and the Committee on Commerce, Science, and Transportation of the Senate that shall include—

"(A) a summary of federally funded sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities;

"(B) a summary of the financial resources allocated to sustainable chemistry initiatives;

"(C) an analysis of the progress made toward achieving the goals and priorities of this Act, and recommendations for future program activities;

"(D) an assessment of the benefits of expanding existing, federally-supported regional innovation and manufacturing hubs to include sustainable chemistry and the value of directing the creation of 1 or more dedicated sustainable chemistry centers of excellence or hubs; and

"(E) an evaluation of steps taken and future strategies to avoid duplication of efforts, streamline interagency coordination, facilitate information sharing, and spread best practices between participating agencies in the Program.

"(2) SUBMISSION TO GAO.—The Interagency Working Group shall also submit the report described in paragraph (1) to the Government Accountability Office for consideration in future Congressional inquiries.".

SEC. 25. STATE PROGRAMS.

Section 28 of the Toxic Substances Control Act (15 U.S.C. 2627) is amended—

(1) in subsection (b)(1)—

(A) in subparagraphs (A) through (D), by striking the comma at the end of each subparagraph and inserting a semicolon; and

(B) in subparagraph (E), by striking ", and" and inserting "; and"; and

(2) by striking subsections (c) and (d).

SEC. 26. AUTHORIZATION OF APPROPRIATIONS.

Section 29 of the Toxic Substances Control Act (15 U.S.C. 2628) is repealed.

SEC. 27. ANNUAL REPORT.

Section 30 of the Toxic Substances Control Act (15 U.S.C. 2629) is amended by striking paragraph (2) and inserting the following:

"(2)(A) the number of notices received during each year under section 5; and

"(B) the number of the notices described in subparagraph (A) for chemical substances subject to a rule, testing consent agreement, or order under section 4;".

SEC. 28. EFFECTIVE DATE.

Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601 note; Public Law 94–469) is amended—

(1) by striking "Except as provided in section 4(f), this" and inserting the following:

"(a) In General.—This"; and

(2) by adding at the end the following:

"(b) Retroactive Applicability.—Nothing in this Act shall be interpreted to apply retroactively to any State, Federal, or maritime legal action commenced prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 4/7/2015 2:09:14 PM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
Subject: RE: have you seen SCHF "support s.697" document?
Attachments: SCHF Position Statement 3.26.15.pdf

From: Jones, Jim [mailto:Jones.Jim@epa.gov]
Sent: Tuesday, April 07, 2015 8:21 AM
To: Black, Jonathan (Tom Udall)
Subject: Re: have you seen SCHF "support s.697" document?

No.

Sent from my iPhone

On Apr 6, 2015, at 5:00 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

> The things needed for them to support.

Safer Chemicals Healthy Families
www.saferchemicals.org

Policy Position of Safer Chemicals Healthy Families on S.697

Safer Chemicals, Healthy Families would support S.697 if all of the following changes were made and no new weakening changes were added:

1. Preemption
   a) Consistent with existing law, timing of preemption for High Priority chemicals should occur at the implementation date of EPA action to restrict a chemical.
   b) Actions taken under state or federal air, water, and waste programs should be clearly exempted.

2. Co-enforcement
   Consistent with existing law, states should be able to enact and co-enforce restrictions identical to EPA actions under Sections 5 and 6.

3. Judicial Review of Low Priority Designations
   The bill should clearly provide citizens with the ability to seek judicial review of EPA Low Priority designations without restrictive time limits.

4. Articles (i.e. consumer products)
   a) The requirement for EPA to demonstrate substantial exposure before it can regulate an article (Section 3A(h)(3)) should be removed.
   b) EPA's ability to require certification of imported articles containing a regulated chemical should be restored to current law.

5. Asbestos and PBTs
   a) The bill should set a deadline for EPA rulemaking on asbestos, eliminating the need for a new safety evaluation.
   b) The bill should replace the "substantial evidence" standard of judicial review with the more common “arbitrary and capricious” standard.
   c) The bill should require EPA to screen for, and expedite risk management for, persistent, bio-accumulative and toxic chemicals.

Message

From: Beck, Nancy [Nancy_Beck@americanchemistry.com]
Sent: 8/3/2015 7:40:49 PM
To: pwilliams@eriskciences.com; Jonathan_Black@tomudall.senate.gov; JerryCouri@mail.house.gov; Farland, William H. [william.farland@research.colostate.edu]; George Gray [gmgray@email.gwu.edu]; Greenwood, Mark A. [mark@greenwood-env.com]; Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]; Walls, Michael [Michael_Walls@americanchemistry.com]; rdenison@edf.org [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b2358277ea84ca2a4375a8b8744a7af-rdenison@edf.org]; Conrad, Jr., James W. [jamie@conradcounsel.com]; gary.marchant@asu.edu [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2af0a20c5bc54776830e3dcb858b0522-gary.marchant@asu.edu]; adunn@ecos.org
CC: Nancy_Beck@americanchemistry.com [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2922d8f69dd84e5386dac0de980c51e5-Nancy_Beck@americanchemistry.com]; Mojica, Andrea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f47e2a2bfbc4434aa9cc1e8c2a385da3-Andrea Mojica]
Subject: TSCA Discussion at SRA Dec 8th
Attachments: SRA TSCA Roundtabledraft05212015.docx

Good Afternoon,
I learned today that the proposal for a TSCA roundtable has been accepted by the Society of Risk Analysis and our specific time is ***Tuesday December 8th 3:30-5pm.***
The meeting will be held at Crystal Gateway Marriott in Crystal City.

I hope this timing will work for everyone so please mark your calendars! I will pass along the official program once it is released and as we get closer to the session date I will arrange a teleconference to further discuss our plans for the roundtable. A working draft of our proposal is attached.

Please let me know if you have any questions. Thank you again for participating!

Regards,
Nancy

Nancy B. Beck, Ph.D., DABT | American Chemistry Council
Senior Director Regulatory Science Policy, Regulatory & Technical Affairs
Nancy_Beck@americanchemistry.com
700 2nd Street, NE | Washington DC | 20002
Office: 202-249-6417
www.americanchemistry.com

SRA Roundtable Discussion on TSCA Reform

Sponsors: SOT/SRA

SRA Specialty Section Sponsors: Risk Policy & Law; Dose Response

Chairs: Nancy B. Beck (American Chemistry Council); Pamela Williams (E Risk Sciences)

Abstract:

The Toxic Substances Control Act (TSCA), the statute by which many chemicals in commerce are regulated in the United States, has been the focus of much recent Congressional attention. Specifically, congress has considered how well the existing statute reflects current scientific knowledge and societal need and there exists bi-partisan agreement that TSCA is in need of reform. In this roundtable, recent advances in both the House and Senate on TSCA Reform bills will be discussed as well as the societal, regulatory, and public policy implications of a revised TSCA bill. Perspectives will include those of risk assessors, risk managers, administrative lawyers, regulators, congressional hill staffers, NGO's and other stakeholders. After brief remarks from roundtable speakers, time will be allotted for a facilitated robust discussion with the audience and panelists.

Unless otherwise noted all speakers are confirmed.

Roundtable Speakers:

1) Current Status of TSCA Reform: Hill staffers:
    a. Jonathan Black, Senate
    b. Jerry Couri, House
2) Innovations in Risk Assessment Approaches in an updated TSCA (including the separation of risk assessment and risk management, role of exposure):
    a. Bill Farland, Colorado State University
    b. George Gray, George Washington University
    c. Mark Greenwood, Greenwood Environmental Counsel PLLC
3) EPA Perspective on Implementation:
    a. Jim Jones, EPA
4) Stakeholder perspectives:
    a. Mike Walls, ACC
    b. Richard Denison, EDF
    c. Jamie Conrad, SOCMA
    d. Gary Marchant, Arizona State University
    e. Alexandra Dunn, ECOS (invited)

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 2/27/2015 5:05:40 PM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
Subject: FW: Latest draft of Udall-Vitter
Attachments: Udall-Vitter Draft P redline 20150227.pdf; Udall-Vitter Draft P redline 20150227.rtf

From: Black, Jonathan (Tom Udall)
Sent: Friday, February 27, 2015 12:05 PM
To: 'Kaiser, Sven-Erik'
Cc: Laura Vaught (vaught.laura@epa.gov); Distefano, Nichole; Karakitsos, Dimitri (EPW)
Subject: Latest draft of Udall-Vitter

Sven, please find attached the latest draft of the Udall-Vitter TSCA reform bill.

We have included several technical changes from our conversations with EPA. We have another draft with even more technical changes, but are concerned that making them at this stage will create more confusion from stakeholders than would be politically feasible. We plan to include the changes as soon as feasible.

This draft also includes some policy changes that will show up in redline/comment form.

We also expect this to be the topic of the legislation at an upcoming EPW hearing.

Thanks,
---Jonathan

WORKING DRAFT P February 27, 2015
Reflecting Changes to the September, 2014 Draft
Bold Text Reflects Changes from Original Text in September, 2014 Draft

Title: To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Chemical Safety Improvement Act".

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(a) of the Toxic Substances Control Act (15 U.S.C. 2601(a)) is amended—

~~(1) in paragraph (2)—~~

~~(A) by striking "injury" and inserting "harm"; and~~

~~(B) by striking "and" at the end;~~

~~(2) by redesignating paragraph (3) as paragraph (4); and~~

~~(3) by inserting after paragraph (2) the following:~~ in subsection (c)—

(1) by designating the existing paragraph as paragraph (1);

(2) by inserting at the end of paragraph (1) (as so redesignated), "as provided under this Act."; and

(3) by inserting at the end of paragraph (1) (as so redesignated), the following:

"(2~~3~~) It is the intent of Congress that reform of this Act in accordance with the amendments made by the Chemical Safety Improvement Act—

"(A) shall be administered in a manner that—

"(i) protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and

"(ii) ensures that appropriate information on chemical substances and mixtures is available to public health officials and first responders in the event of an emergency; and

"(B) shall not displace or supplant common law rights of action or remedies for civil relief~~; and~~".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

Formatted: Indent: Left: 0"

Comment [B1]: Existing TSCA and sections of TSCA not amended by this Act use "injury." The change thus conforms the bill to existing term. Change reflected throughout the bill

Comment [B2]: Properly places this text in the Intent of Congress subsection of section 2.

Comment [B3]: Corrects typo

(1) by redesignating paragraphs (7), (8), (9), (10) , (11), (12), (13), and (14) as paragraphs (~~7~~9), (~~9~~10), (10~~1~~), (13), (1~~7~~4), (1~~8~~9), and (19~~2~~0), ~~and (21),~~ respectively;

(2) by inserting after paragraph (6) the following:

~~"(7) INFORMATION.—The term 'information' means any qualitative, quantitative, or descriptive facts, data, analysis, or assessment related to chemical hazards, use, or exposure (including the nature and extent of exposure to a chemical substance), including from health and safety studies.~~

"(~~7~~8) ~~INTENDED OR REASONABLY ANTICIPATED~~ CONDITIONS OF USE.—The term ~~'intended or reasonably anticipated~~ 'conditions of use' means the intended, known, or reasonably foreseeable circumstances the Administrator determines ~~are those under which~~ a chemical substance is ~~is intended, reasonably known, or reasonably anticipated to be~~ manufactured, processed, distributed in commerce, used, ~~and~~or disposed of.";

(3) by inserting after paragraph (10~~1~~) (as so redesignated) the following:

"(1~~2~~1) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.—The term 'potentially exposed or susceptible population' means 1 or more groups—

"(A) of individuals within the general population who may be—

"(i) differentially exposed to chemical substances under the ~~intended or reasonably anticipated~~ conditions of use; or

"(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

"(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; and

(4) by inserting after paragraph (1~~3~~4) (as so redesignated) the following:

~~"(15) PUBLICLY AVAILABLE.—~~

~~"(A) IN GENERAL.—The term 'publicly available', with respect to information, means information that is—~~

~~"(i) generally accessible and available to the general public; or~~

~~"(ii) in the public domain.~~

~~"(B) INCLUSIONS.—The term 'publicly available', with respect to information, includes information that has been published in periodicals, books, print, an electronic format, or other media available for general distribution to any member of the public.~~

"(1~~4~~6) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the ~~intended or reasonably anticipated~~ conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.

"(1~~5~~7) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the ~~intended or reasonably anticipated~~ conditions of use.

"(1~~7~~8) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of

Comment [B4]: Redesignated as a result of two definitions struck below.

Comment [B5]: Definition not necessary

Comment [B6]: Modifications to the definition of intended use eliminate the need to make this clarification, throughout.

Comment [B7]: Definition not necessary

~~harm~~ injury to ~~human~~ health or the environment will result from exposure to a chemical substance under the ~~intended or reasonably anticipated~~ conditions of use, including no unreasonable risk of ~~harm~~ injury to—

Comment [B8]: Existing TSCA and sections of TSCA not amended by this Act use "health" rather than "human health." Change reflected throughout the bill.

"(A) the general population; or

"(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

The Toxic Substances Control Act is amended by inserting after section 3 (15 U.S.C. 2602) the following:

"SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

"(a) Definition of Guidance.—In this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.

"(b) Deadline.—Not later than 2 years after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.

"(c) Use of Science.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance on the use of science in making decisions under sections 4, 4A, 5, and 6.

"(2) GOAL.—A goal of the policies and procedures described in paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) REQUIREMENTS.—The policies, procedures, and guidance issued under this section shall describe the manner in which the Administrator shall ensure that —

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;

"(B) to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.

"(e) Review.—Not later than 5 years after the date of enactment of this section, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(1) review the adequacy of any policies, procedures, and guidance developed under this section, including animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this Act; and

"(2) after providing public notice and an opportunity for comment, revise the policies, procedures, and guidance if necessary to reflect new scientific developments or understandings.

"(f) Sources of Information.—In making any decision with respect to a chemical substance under section 4, 4A, 5, or 6, the Administrator shall take into consideration information relating to the hazards and exposures of a chemical substance under the ~~intended or reasonably anticipated~~ conditions of use that is reasonably available to the Administrator, including information that is—

"(1) submitted to the Administrator pursuant to any ~~regulation~~rule, consent agreement, order, or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act, by—

Comment [B9]: Existing TSCA uses the term "rule". Change conformed throughout the bill

"(A) manufacturers or processors of a substance;

"(B) the public;

"(C) other Federal departments or agencies; or

"(D) the Governor of a State or a State agency with responsibility for protecting health or the environment;

"(2) submitted to a governmental entity in any jurisdiction pursuant to a governmental requirement relating to the protection of ~~human~~ health or the environment; or

"(3) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible by the Administrator.

"(g) Exposure Information.—If the Administrator obtains information related to exposures or releases of a chemical substance that may be prevented or reduced under another Federal law, including laws not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.

Comment [B10]: Inserted to ensure that exposure/release information obtained by Administrator is shared appropriately.

"(h) Testing of Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator shall establish policies and procedures for the testing of chemical substances or mixtures under section 4.

"(2) GOAL.—A goal of the policies and procedures established under paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) CONTENTS.—The policies and procedures established under paragraph (1) shall—

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential;

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations;

"(C) require the Administrator to consult with the Director of the National Institute for Occupational Safety and Health prior to prescribing epidemiologic studies of employees; and

"(D) prior to adopting a requirement for testing using vertebrate animals, require the Administrator to take into consideration, as appropriate and to the extent practicable, reasonably available—

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

"(iii) high-throughput screening methods and the prediction models of those methods; and

"(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.

"(4) TIERED TESTING.—

"(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.

"(B) SCREENING-LEVEL TESTS.—

"(i) IN GENERAL.—The screening-level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.

"(ii) USE.—Screening-level tests shall be used—

"(I) to screen chemical substances or mixtures for potential adverse effects; and

"(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.

"(C) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for safety assessments or safety determinations, the Administrator may require more advanced tests for potential ~~human~~ health or environmental effects or exposure potential.

"(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

"(~~i~~h) Safety Assessments and Safety Determinations.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(C) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall identify the substances subject to safety assessments and safety determinations to be completed that year.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(A) IN GENERAL.—The Administrator shall establish, by ~~regulation~~rule, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

"(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

"(C) MINIMUM REQUIREMENTS.—At a minimum, the policies and procedures under this paragraph shall—

"(i) describe—

"(I) the manner in which the Administrator will identify informational needs and seek that information from the public;

"(II) the information (including draft safety assessments) that may be submitted by interested individuals or entities, including States; and

"(III) the criteria by which that information will be evaluated;

"(ii) require the Administrator—

"(I)(aa) to define the scope of the safety assessment and determination to be conducted under section 6, including ~~identify~~ the hazards, exposures, ~~intended or reasonably anticipated~~ conditions of use, and potentially exposed and susceptible populations that the Administrator expects to consider in a safety assessment;

"(bb) to explain the basis for ~~those identifications~~the scope of the safety assessment and determination; and

"(cc) to accept comments regarding the ~~identifications~~scope of the safety assessment and determination; and

"(II)(aa) to identify the items described in subclause (I) that the Administrator has considered in the final safety assessment; and

"(bb) to explain the basis for the consideration of those items;

"(iii) describe the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the ~~intended or reasonably anticipated~~ conditions of use will be considered, and explain the basis for that consideration in the final safety assessment;

"(iv) require that each safety assessment and safety determination shall include—

"(I) a description of the weight of the scientific evidence of risk; and

"(II) a summary of the information regarding the impact on ~~human~~ health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies; ~~and~~

"(v) establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination; and

"(vi) when relevant information is provided to or otherwise made available to the Administrator, consider the extent of federal regulation under other federal laws.

Comment [B11]: Modified to make clear that the scope of safety assessments and determinations is subject to notice and comment. Conforms to changes made in section 6(a).

Comment [B12]: Inserted to ensure that Administrator considers information made available regarding other federal regulation that may be applicable.

"(D) GUIDANCE.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall develop guidance to assist interested persons in developing draft safety assessments and other information for submission to the Administrator, which may be considered at the discretion of the Administrator.

"(ii) REQUIREMENT.—The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing a draft assessment for consideration by the Administrator.

"(3) Articles.— If the Administrator intends to prohibit or otherwise restrict an article on the basis of a chemical substance contained in that article, the Administrator shall have evidence of significant exposure to the chemical substance from such article.

Comment [B13]: Provides a consistent regulatory basis for articles which may be affected by a safety assessment/determination and rule.

Formatted: Indent: Left: 0.17"

"(~~i~~j) Publicly Available Information.—Subject to section 14, the Administrator shall—

"(1) make publicly available a nontechnical summary, and the final version, of each safety assessment and safety determination;

"(2) provide public notice and an opportunity for comment on each proposed safety assessment and safety determination; and

"(3) make public in a final safety assessment and safety determination—

"(A) the list of studies considered by the Administrator in carrying out the safety assessment or safety determination; and

"(B) the list of policies, procedures, and guidance that were followed in carrying out the safety assessment or safety determination.

"(~~j~~k) Consultation With Science Advisory Committee on Chemicals.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish an advisory committee, to be known as the 'Science Advisory Committee on Chemicals' (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, on the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

Comment [B14]: Expands membership of Advisory Committee

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(5) RELATIONSHIP TO OTHER LAW.—All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).".

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking subsections (a), (b), (c), (d), and (g);

(2) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively;

(3) in subsection (f) (as so redesignated)—

(A) by striking "rule" each place it appears and inserting "~~regulation~~rule, testing

consent agreement, or order";

(B) by striking "under subsection (a)" each place it appears and inserting "under this subsection"; and

(C) in paragraph (1)(B), in the last sentence, by striking "rulemaking";

(4) in subsection (g) (as so redesignated)—

(A) in the first sentence, by striking "from cancer, gene mutations, or birth defects"; and

(B) by striking the last sentence; and

(5) by inserting before subsection (f) (as so redesignated) the following:

"(a) Development of New Information on Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section if the Administrator determines that the information is necessary—

"(A) to review a notice under section 5(d) or to perform a safety assessment or safety determination under section 6;

Comment [B15]: Clarifies scope of testing authority

"(B) to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4) or under a rule promulgated under section 6(d)(3);

Comment [B16]: Clarifies scope of testing authority

"(C) pursuant to section 12(a)(4); or

"(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

"(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.

"(B) PROHIBITION.—Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.

"(C) LIMITATION.—The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

"(3) FORM.—Subject to section 3A(hf), the Administrator may require the development of ~~test data and~~ information described in paragraph (1) or (2) by—

"(A) promulgating a ~~regulation~~rule;

"(B) entering into a testing consent agreement; or

"(C) issuing an order.

"(4) CONTENTS.—

"(A) IN GENERAL.—A ~~regulation~~rule, testing consent agreement, or order issued under this subsection shall include—

"(i) identification of the chemical substance or mixture for which testing is required;

"(ii) identification of the persons required to conduct the testing;

"(iii) test protocols and methodologies for the development of test data and information for the chemical substance or mixture, including specific reference to reliable nonanimal test procedures; and

"(iv) specification of the period within which individuals and entities required to conduct the testing shall submit to the Administrator the information developed in accordance with the procedures described in clause (iii).

"(B) CONSIDERATIONS.—In determining the procedures and period to be required under subparagraph (A), the Administrator shall take into consideration—

"(i) the relative costs of the various test protocols and methodologies that may be required; and

"(ii) the reasonably foreseeable availability of facilities and personnel required to perform the testing.

"(b) Statement of Need.—

"(1) IN GENERAL.—In promulgating a ~~regulation~~rule, entering into a testing consent agreement, or issuing an order for the development of additional information (including information on exposure or exposure potential) pursuant to this section, the Administrator shall—

"(A) identify the need intended to be met by the ~~regulation~~rule, agreement, or order;

"(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of vertebrate animals.

"(2) EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an order is warranted instead of promulgating a ~~regulation~~ rule or entering into a testing consent agreement.

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a description of—

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

"(ii) the extent to which the Administrator has obtained or attempted to obtain the information through voluntary submissions; and

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

"(I) animal-based studies; and

"(II) emerging methods and models; and

"(B) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) after providing an opportunity for public comment, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information ~~used in safety assessments and safety determinations under section 6~~under this title that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

"(C) beginning on the date that is 5 years after the date of enactment of the Chemical Safety Improvement Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation; and

"(~~C~~D) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing under this title~~safety assessment or safety determination under section 6~~.

Comment [B17]: Clarifies that strategic plan applies to entire title

Comment [B18]: Ensures strategic plan is referenced as test plans are developed

Comment [B19]: Clarifies that R&D efforts extend to all testing under this title

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(d) Testing Requirements.—

"(1) IN GENERAL.—The Administrator may require the development of information by—

"(A) manufacturers and processors of the chemical substance or mixture; and

"(B) persons that begin to manufacture or process the chemical substance or mixture—

"(i) after the effective date of the ~~regulation~~rule, testing consent agreement, or order; but

"(ii) subject to paragraph (3), before the period ending on the date that is 180 days after the end of the period described in this section.

"(2) DESIGNATION.—The Administrator may permit 2 or more persons identified in subparagraph (A) or (B) of paragraph (1) to designate 1 of the persons or a qualified third party—

"(A) to develop the information; and

"(B) to submit the information on behalf of the persons making the designation.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—A person otherwise subject to a ~~regulation~~rule, testing consent agreement, or order under this section may submit to the Administrator an application for an exemption on the basis that the information is being developed by a person designated under paragraph (2).

"(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

"(i) IN GENERAL.—If the Administrator accepts an application submitted under subparagraph (A), the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as

agreed to between the applicant and the designee.

"(ii) ARBITRATION.—If the applicant and a person designated under paragraph (2) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.

"(C) TERMINATION.—If, after granting an exemption under this paragraph, the Administrator determines that a person covered by the exemption has failed to comply with the ~~regulation~~rule, testing consent agreement, or order, the Administrator shall—

"(i) by order, terminate the exemption; and

"(ii) notify in writing each person that received an exemption of the requirements with respect to which the exemption was granted.

"(e) Transparency.—Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders and all information submitted under this section.".

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the third sentence by striking "section 4(e)" and inserting "section 4(f)".

SEC. 6. PRIORITIZATION SCREENING.

The Toxic Substances Control Act is amended by inserting after section 4 (15 U.S.C. 2603) the following:

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) Establishment and List of Substances.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish, by ~~regulation~~rule, a risk-based screening process and **explicit** criteria for identifying existing chemical substances that are—

"(A) a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances'); and

"(B) a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').

"(2) INITIAL LIST OF HIGH- **AND LOW-**PRIORITY SUBSTANCES.—

"(A) IN GENERAL.—Before the date of promulgation of the ~~regulation~~ rule under paragraph (1) and not later than 180 days after the date of enactment of this section, the Administrator—

"(i) shall take into consideration and publish an initial list of high-priority substances **and low-priority substances**; and

"(ii) pursuant to section 6(b)~~(2)~~, may initiate or continue safety assessments and safety determinations for those ~~chemical~~ **high-priority** substances.

"(B) REQUIREMENTS.—

"(i) The initial list of ~~high-priority~~ chemical substances shall contain at least 10 ~~high priority substances~~, at least 5 of which are drawn from the list of chemical substances identified by the Administrator in the October, 2014 TSCA Work Plan and subsequent updates, ~~chemical high-priority substances and at least 10~~ **low-priority** substances; and

"(ii) insofar as possible, at least 50 percent of all substances subsequently identified by the Administrator as high-priority substances shall be drawn from the list of chemical substances identified by the Administrator in the October, 2014 TSCA Work Plan and subsequent updates, until all Work Plan chemicals have been designated under this subsection.

"(C) Additional Chemical Reviews.—The Administrator shall, as soon as practicable and no later than 5 years from the date of enactment of this Act, add additional high-priority substances sufficient to ensure that at least 20 high-priority substances have undergone or are undergoing safety assessments and determinations, and additional low-priority substances sufficient to ensure that at least 20 low-priority substances have been designated.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator shall take into consideration active substances, as determined under section 8, which may include chemical substances on the interim list of active substances established under that section.

"(ii) INACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator may take into consideration inactive substances, as determined under section 8, that the Administrator determines—

"(I)(aa) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) have the potential for high hazard and widespread exposure; or

"(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) with respect to which there exists the potential for residual high hazards or widespread exposures not otherwise addressed by the regulatory or other action.

"(iii) REPOPULATION.—

"(I) IN GENERAL.—On the completion of a safety determination under section 6 for a chemical substance, the Administrator shall remove the chemical substance from the list of high-priority substances established under this subsection.

"(II) ADDITIONS.—The Administrator shall add at least 1 chemical substance to the list of high-priority substances for each chemical substance removed from the list of high-priority substances established under this

Formatted: Indent: Left: 0.83", First line: 0.33"

Formatted: Font: Bold

Comment [B20]: Ensures that at least 50 percent of initial and subsequent chemicals are drawn from TSCA Work Plan (which identified chemicals on the basis of hazard, exposure, persistence and bioaccumulative characteristics) are addressed, until all Work Plan chemicals are designated.

Comment [B21]: Accelerates throughput in a time frame consistent with anticipated schedule for safety assessments on initial list, development of fee regulation and collection of fees.

Formatted: Indent: Left: 0.5", First line: 0.33"

subsection, until a safety assessment and safety determination is completed for all high-priority substances.

"(III) LOW-PRIORITY SUBSTANCES.—If a low-priority substance is subsequently designated as a high-priority substance, the Administrator shall remove that substance from the list of low-priority substances.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) not later than 180 days after the effective date of the final ~~regulation~~ rule under paragraph (1), begin the prioritization screening process; and

"(II) make every effort to complete the ~~prioritization screening~~ **designation** of all active **substances as high-priority substances or low-priority** substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a ~~regulation~~rule, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical substance as a high-priority substance or low-priority substance.

"(iii) CONSIDERATION.—

"(I) IN GENERAL.—The Administrator shall screen substances **and designate high-priority substances** taking into consideration the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in a timely manner.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.

"(C) SCREENING OF CATEGORIES OF SUBSTANCES.—The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate **designations of high-priority substances and low-priority substances and** safety assessments and safety determinations **for high-priority substances**.

"(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—Not less frequently than once each year, the Administrator shall publish a list of chemical substances that—

"(i) are being considered in the prioritization screening process and the status of the chemical substances in the prioritization process, including those chemical substances for which prioritization decisions have been deferred; and

"(ii) are designated as high-priority substances or low-priority substances, including the bases for such designations.

"(4) CRITERIA.—The criteria described in paragraph (1) shall account for—

"(A) the recommendation of the Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances

appropriate for prioritization screening;

"(B) the hazard and exposure potential of the chemical substance (or category of substances), including specific scientific classifications and designations by authoritative governmental entities;

"(C) the ~~intended or reasonably anticipated~~ conditions of use or significant changes in the conditions of use of the chemical substance;

"(D) evidence and indicators of exposure potential to humans or the environment from the chemical substance, including potentially exposed or susceptible populations;

"(E) the volume of a chemical substance manufactured or processed;

"(F) whether the volume of a chemical substance as reported under a ~~regulation~~ rule promulgated pursuant to section 8(a) has significantly increased or decreased during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance;

"(G) the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

"(H) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a low-priority substance.

"(b) Prioritization Screening Process and Decisions.—

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall include a requirement that the Administrator shall—

"(A) identify the chemical substances being considered for prioritization;

"(B) request interested persons to supply information regarding the chemical substances being considered;

"(C) apply the criteria identified in subsection (a)(4); and

"(D) subject to paragraph (5) and using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.

"(2) INTEGRATION OF INFORMATION.—The prioritization screening decision regarding a chemical substance shall integrate any hazard and exposure information relating to the chemical substance that is available to the Administrator.

"(3) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(A) shall identify as a high-priority substance a chemical substance that, relative to other chemical substances, the Administrator determines has the potential for high hazard and widespread exposure;

"(B) may identify as a high-priority substance a chemical substance that, relative to other chemical substances, the Administrator determines has the potential for high hazard or widespread exposure; and

"(C) may identify as a high-priority substance an inactive substance, as determined under subsection (a)(3)(A)(ii) and section 8(b), that the Administrator determines warrants a safety assessment and safety determination under section 6.

"(4) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that the chemical substance is likely to meet the applicable safety standard.

"(5) DEFERRING A DECISION.—If the Administrator determines that additional information is required to establish the priority of a chemical substance under this section, the Administrator may defer the prioritization screening decision for a reasonable period—

"(A) to allow for the submission of additional information by an interested person and for the Administrator to evaluate the additional information; or

"(B) to require the development of information pursuant to a ~~regulation~~rule, testing consent agreement, or order issued under section 4(a)(2).

"(6) DEADLINES FOR SUBMISSION OF INFORMATION.—If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of the information.

"(7) NOTICE AND COMMENT.—The Administrator shall—

"(A) publish the proposed decisions made under paragraphs (3), (4), and (5) and the basis for the decisions; and

"(B) provide an opportunity for public comment.

"(8) REVISIONS OF PRIOR DESIGNATIONS ~~BASED ON NEW INFORMATION~~.—

"(A) IN GENERAL.—At any time, and at the discretion of the Administrator, the Administrator may revise the designation of a chemical substance as a high-priority substance or a low-priority substance based on ~~new~~ information ~~made~~ available to the Administrator after the date of the determination under paragraph (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.

"(9) **OTHER INFORMATION RELEVANT TO PRIORITIZATION.—**

"(A) IN GENERAL.—If, after the date of enactment of the Chemical Safety Improvement Act, a State proposes an administrative action or **enacts a statute or takes an administrative action to ~~restrict or~~ prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not as designated a high-priority substance, the Governor or State agency with responsibility for implementing the statute or**

administrative action shall notify the Administrator.

"(B) REQUESTS FOR INFORMATION.—Following receipt of a notification provided under subparagraph (A), the Administrator may request any available information from the Governor or the State agency with respect to—

"(i) scientific evidence related to the hazards, exposures and risks of the chemical substance under the ~~intended~~ conditions of use which the statute or administrative action is intended to address;

"(ii) any State or local conditions which warranted the statute or administrative action;

"(iii) the statutory or administrative authority on which the action is based; and

"(iv) any other available information relevant to the prohibition or other restriction ~~or prohibition~~, including information on any alternatives considered and their hazards, exposures, and risks.

Comment [B22]: Reference to "prohibition or other restriction", or "prohibit or otherwise restrict" conformed throughout the bill for clarity

"(C) PRIORITIZATION SCREENING.—The Administrator shall conduct a prioritization screening under this subsection for all substances that—

"(i) are the subject of notifications received under subparagraph (A); and

"(ii) the Administrator determines—

"(I) are likely to have significant health or environmental impacts;

"(II) are likely to have significant impact on interstate commerce; or

"(III) have been subject to a ~~restriction or~~ a prohibition or other restriction under a statute or administrative action in 2 or more States.

"(D) AVAILABILITY TO PUBLIC.—Subject to section 14 and any applicable State law regarding the protection of confidential information provided to the State or to the Administrator, the Administrator shall make information received from a Governor or State agency under subparagraph (A) publicly available.

"(E) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall preempt a State statute or administrative action, require approval of a State statute or administrative action, or ~~subject a State to~~apply section 15 to a State.

"(10) REVIEW.—Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Administrator shall—

"(A) review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and

"(B) if necessary, modify the prioritization screening process.

"~~(10)~~**"(11)** EFFECT.—Subject to section 18, a designation by the Administrator under this section with respect to a chemical substance shall not affect—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance; or

"(B) the regulation of those activities.

~~"(c) Expedited Prioritization Screening.—~~ **Screening Requested by States.—**

Comment [B23]: Struck by request

~~"(1) IN GENERAL.—Not later than 180 days after the date on which the Administrator receives from the Governor of a State or a State agency with responsibility for protecting health and the environment a recommendation and relevant information justifying that an active a substance be identified **designated under paragraph (3) or (4) of subsection (b)** as a high-priority substance or a low-priority substance, the Administrator shall make a prioritization screening decision for the active substance.~~

~~"(2) LIMITATION.—The Governor of a State or a State agency with responsibility for protecting health and the environment may annually recommend not more than 2 chemical substances for prioritization screening under paragraph (1).~~

~~"(3) RECOMMENDATION.—Notwithstanding subsection (b)(8), a recommendation by the Governor of a State or a State agency with responsibility for protecting health and the environment with respect to a chemical substance that has been previously prioritized shall not be required to be based on new information.~~

~~"(4) NOTICE AND COMMENT.—The public shall be provided notice and an opportunity to comment regarding the recommendations submitted under this subsection.~~

~~"(5) EXPLANATION OF REASONS.—The Administrator shall—~~

~~"(A) make available to the Governor or State agency, as applicable, and to the public a brief explanation of the reasons for—~~

~~"(i) identifying a chemical substance recommended by the Governor or State agency for prioritization screening as a high-priority substance or a low-priority substance; or~~

~~"(ii) deferring a prioritization screening decision; and~~

~~"(B) identify the information relied on in making that identification.~~

"(~~c~~d) ~~Treatment.—Except as provided in section 18(e)(6)(B), an~~ **Additional Priorities for Safety Assessments and Determinations.—**

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall—

"(A) include a process by which a manufacturer or processor of an active chemical substance that has not been designated a high-priority substance, or that has not been subject to or is not in the process of a prioritization screening by the Administrator, may request that the Administrator designate the substance for a safety assessment and safety determination, subject to the payment of fees pursuant to section 26(b)(3)(E); and

"(B) provide guidance to submitters on the information to be provided in such requests, and specify the criteria the Administrator shall use to determine whether or not to grant such a request, which shall include whether the substance is subject to restrictions imposed by statutes enacted or administrative actions taken by 1 or more States on the manufacture, processing, distribution in

commerce, or use of the substance.

"(2) PREFERENCE.—Subject to paragraph (3), in deciding whether to grant requests under this subsection the Administrator shall give a preference to requests concerning substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

"(3) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

"(A) not more than 15 percent of the total number of substances designated to undergo safety assessments and safety determinations under this section are substances designated under the process and criteria pursuant to paragraph (1); and

"(B) the resources allocated to conducting safety assessments and safety determinations for additional priorities designated under this subsection are proportionate to the number of such substances relative to the total number of substances designated to undergo safety assessments and safety determinations under this section.

"(4) REQUIREMENTS.—

"(A) IN GENERAL.—The public shall be provided notice and an opportunity to comment on requests submitted under this subsection.

"(B) DECISION BY ADMINISTRATOR.—Not later than 180 days after the date on which the Administrator receives a request under this subsection, the Administrator shall decide whether or not to grant the request.

"(C) ASSESSMENT AND DETERMINATION.—If the Administrator grants a request under this subsection, the safety assessment and safety determination—

"(i) shall be conducted in accordance with the deadlines and other requirements of sections 3A(~~ii~~ii) and 6; and

"(ii) shall not be expedited or otherwise subject to special treatment relative to high-priority substances designated pursuant to subsection (b)(3) that are undergoing safety assessments and safety determinations.

"(5) EXCEPTIONS.—Requests granted under this subsection shall not be subject to subsection (a)(3)(A)(iii) or section 18(b).".

~~"(e) Treatment.—An action by the Administrator under this section shall not be—~~

~~"(1) considered to be a final agency action; or~~

~~"(2) subject to judicial review.".~~

SEC. 7. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.";

(2) by striking subsection (b);

(3) by redesignating subsection (a) as subsection (b);

(4) by redesignating subsection (i) as subsection (a) and moving the subsection so as to appear at the beginning of the section;

(5) in subsection (b) (as so redesignated)—

(A) in the subsection heading, by striking "In General" and inserting "Notices"; and

(B) in paragraph (1), in the matter following subparagraph (B)—

(i) by striking "subsection (d)" and inserting "subsection (b)"; and

(ii) by striking "and such person complies with any applicable requirement of subsection (b)";

(6) by redesignating subsections (c) and (d) as subsection (d) and (c), respectively, and moving subsection (c) (as so redesigned) so as appear after subsection (b) (as redesignated by paragraph (3));

(7) in subsection (c) (as so redesignated)—

(A) by striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—The notice required by subsection (a) shall include, with respect to a chemical substance—

"(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

"(B) information regarding ~~intended or reasonably anticipated~~ conditions of use and reasonably anticipated exposures.";

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking "or of data under subsection (b)";

(ii) in subparagraph (A), by adding "and" after the semicolon at the end;

(iii) in subparagraph (B), by striking "; and" and inserting a period; and

(iv) by striking subparagraph (C); and

(C) in paragraph (3), by striking "subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "subsection (b) and for which the notification period prescribed by subsection (b) or (d)";

(8) by striking subsection (d) (as redesignated by paragraph (6)) and inserting the following:

"(d) Review of Notice.—

"(1) INITIAL REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall—

"(i) conduct an initial review of the notice;

"(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

"(iii) make any necessary determination under paragraph (3).

"(B) EXTENSION.—Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.

"(2) INFORMATION SOURCES.—In evaluating a notice under paragraph (1), the Administrator shall take into consideration—

"(A) any relevant information identified in subsection (c)(1); and

"(B) any other relevant additional information available to the Administrator.

"(3) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), and based on the information described in paragraph (2), the Administrator shall determine that—

"(A) the relevant chemical substance or significant new use is not likely to meet the safety standard, in which case the Administrator shall take appropriate action under paragraph (45);

"(B) the relevant chemical substance or significant new use is likely to meet the safety standard, in which case the Administrator shall allow the review period to expire without additional restrictions; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (5).

"(4) RESTRICTIONS.—

"(A) IN GENERAL.—

"(i) If the Administrator makes a determination under subparagraph (A) or (C) of paragraph (3) with respect to a notice submitted under subsection (b)—

"(I) the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, as appropriate, shall prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the restrictions specified in the consent agreement or order that the Administrator determines are sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard; and

Formatted: Indent: Left: 0.83"

Formatted: Indent: Left: 1"

"(II) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, except in compliance with the restrictions specified in the consent agreement or order.

"(ii) If the Administrator makes a determination under subparagraph (B) of paragraph (3) with respect to a chemical substance or significant new use for which a notice was submitted under subsection (b), at the end of the applicable period for review under paragraph (1), the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use.

"(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall—

"(i) take into consideration whether to promulgate a ~~regulation~~ rule pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance, or of the chemical substance for a new use, that is not in compliance with the restrictions imposed by the consent agreement or order; and

"(ii)(I) initiate a rulemaking described in clause (i); or

"(II) publish a statement describing the reasons of the Administrator for not initiating a rulemaking.

"(C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include, as appropriate—

"(i) a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the warnings and instructions to be prescribed by the Administrator;

"(ii) a requirement that manufacturers ~~and~~or processors of the chemical substance shall—

"(I) make and retain records of the processes used to manufacture or process, as applicable, the chemical substance; or

"(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, use, or disposal, as applicable, of the chemical substance, subject to section 4;

"(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

"(I) in general; or

"(II) for a particular use;

"(iv) a prohibition or other ~~regulation~~ restriction of—

Comment [B24]: Clarifies circumstances under which a new chemical or significant new use subject to consent agreement or order may be commenced.

Formatted: Indent: Left: 0.83"

Comment [B25]: Clarifies that substances likely to meet the safety standard can proceed to manufacture.

"(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

"(II) any method of commercial use of the chemical substance; or

"(III) any method of disposal of the chemical substance; or

"(v) a prohibition or other ~~appropriate~~ restriction on the manufacture, processing, or distribution in commerce of the chemical substance—

"(I) in general; or

"(II) for a particular use.

"(D) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

"(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(C) may promulgate a ~~regulation~~rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

"(D) on receipt of information the Administrator finds supports the determination under paragraph (3), shall promptly make the determination.

"(6) REGULATION PENDING DEVELOPMENT OF INFORMATION.—Subject to paragraph (4)(B), the Administrator may permit manufacture for commercial purposes of a chemical substance to commence pending receipt of the additional information, subject to compliance with any restrictions under paragraph (4) determined by the Administrator to be sufficient to ensure that the chemical substance is likely to meet the safety standard.

"(7) COMMENCEMENT OF MANUFACTURE.—Subject to paragraphs (4), (5), and (6), at the end of the applicable period for review under paragraph (1), the submitter of a notice under subsection (a) may commence manufacture for commercial purposes of a chemical substance or a chemical substance for a significant new use.";

(9) by striking subsections (e) through (g) and inserting the following:

"(e) Notice of Commencement.—

"(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer ~~or processor~~ that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer ~~or processor~~ shall submit to the Administrator a notice of commencement that identifies—

Comment [B26]: Notices of commencement cannot be made by a processor. Conforms to existing law.

"(A) the name of the manufacturer ~~or processor~~; and

"(B) the initial date of nonexempt commercial manufacture.

"(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

"(f) Further Evaluation.—The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—

"(1) a notice of commencement for a chemical substance under subsection (c); or

"(2) new information regarding the chemical substance.

"(g) Transparency.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, consent agreements, ~~regulations~~rules, and orders of the Administrator; and

"(2) all information submitted or issued under this section.";

(10) in subsection (h)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking "(a) or";

(B) by striking paragraph (2);

(C) by redesignating paragraphs (3) through (6) as paragraphs (2) through (5), respectively;

(D) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking "subsections (a) and (b)" and inserting "subsection (b)";

(E) in paragraph (3) (as so redesignated)—

(i) in the first sentence, by striking "will not present an unreasonable risk of injury to health or the environment" and inserting "will meet the safety standard"; and

(ii) by striking the second sentence;

(F) in paragraph (4) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (b)"; and

(G) in paragraph (5) (as so redesignated), in the first sentence, by striking "paragraph (1) or (5)" and inserting "paragraph (1) or (4).~~;~~", ~~; and~~

~~(11) by adding at the end the following:~~

~~"(i) Prior Actions.—Nothing in this section requires the Administrator to modify or withdraw any regulation or order promulgated pursuant to this section before the date of enactment of the Chemical Safety Improvement Act.".~~

Formatted: Indent: Left: 0.67"

Comment [B27]: Moved to Section 26(h)

SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections (g~~h~~) and (h~~i~~), respectively;

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) shall, as soon as practicable and not later than 6 months after the date on which a chemical substance is designated as a high-priority substance, define the scope of the safety assessment and determination to be conducted pursuant to this section, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that the Administrator expects to consider;

"(3) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(4~~3~~) shall complete a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

"(5~~4~~) shall promulgate a final ~~regulation~~ rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; and

"(6~~5~~) may extend any deadline under this subsection for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under paragraphs (4~~3~~) and (5~~4~~) and any deferral under subsection (c)(2) does not exceed 2 years.

"(b) Prior Actions.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination that was initiated before the date of enactment of the Chemical Safety Improvement Act, prior to the effective date of the policies and procedures required to be established by the Administrator under section 3A or 4A.

"(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or ~~regulation~~ rule solely because the action was completed prior to the completion of a policy or procedure established under

Comment [B28]: Establishes a date by which the scope of the safety assessment and determination must be defined. Conforming change made in section 18.

section 3A or 4A, and the validity of a completed assessment, determination, or ~~regulation~~ rule shall not be determined based on the content of such a policy or procedure.

"(c) Safety Determinations.—

"(1) IN GENERAL.—Based on a review of the information available to the Administrator, including draft safety assessments submitted by interested persons, the Administrator shall determine that—

"(A) the relevant chemical substance meets the safety standard;

"(B) the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by ~~regulation~~ rule under subsection (d)—

"(i) impose restrictions necessary to ensure that the chemical substance meets the safety standard under the intended or reasonably anticipated conditions of use; or

"(ii) if the safety standard cannot be met with the application of restrictions, ban or phase out the chemical substance, as appropriate; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is necessary to make a safety assessment or safety determination for a high-priority substance, the Administrator—

"(A) shall provide an opportunity for interested persons to submit the additional information;

"(B) may promulgate a ~~regulation~~rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

"(C) may defer, for a reasonable period consistent with the deadlines described in subsection (a), a safety assessment and safety determination until after receipt of the information; and

"(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety determination, shall make a determination under paragraph (1).

"(3) ESTABLISHMENT OF DEADLINE.—In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.

"(d) ~~Regulation~~Rule.—

"(1) IMPLEMENTATION.—If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a ~~regulation~~ rule establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

"(2) SCOPE.—The ~~regulation~~ rule promulgated pursuant to this subsection—

"(A) may—

"(i) apply to mixtures containing the chemical substance, as appropriate; and

"(ii) exempt replacement parts for articles manufactured prior to the applicable compliance deadline; and

"(B) shall include dates by which compliance is mandatory, which—

"(i) shall be as soon as practicable; and

"(ii) as determined by the Administrator, may vary for different affected persons.

"(C) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(3) RESTRICTIONS.—A restriction under paragraph (1) may include, as appropriate—

"(A) subject to section 18, a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the warnings and instructions to be prescribed by the Administrator;

"(B) a requirement that manufacturers ~~and~~ or processors of the chemical substance shall—

"(i) make and retain records of the processes used to manufacture or process the chemical substance;

"(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or

"(iii) monitor or conduct tests that are reasonably necessary to ensure compliance with the requirements of any ~~regulation~~ rule under this subsection;

"(C) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

"(D) a requirement to ban or phase out, or any other ~~regulation~~ rule regarding, the manufacture, processing, or distribution in commerce of the chemical substance for—

"(i) a particular use;

"(ii) a particular use at a concentration in excess of a level specified by the Administrator; or

"(iii) all uses;

"(E) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—

"(i) a particular use; or

"(ii) a particular use at a concentration in excess of a level specified by the Administrator;

"(F) a requirement to ~~restrict,~~ ban, ~~or~~ phase out, or ~~any~~ otherwise restrict ~~regulation of,~~ any method of commercial use of the chemical substance;

"(G) a requirement to ~~restrict,~~ ban, ~~or~~ phase out, or ~~any~~ otherwise restrict ~~regulation of,~~ any method of disposal of the chemical substance or any article containing the chemical substance; and

"(H) a requirement directing manufacturers or processors of the chemical substance to give notice of ~~unreasonable risks of harm~~ the Administrator's determination under subsection (c)(1)(B) to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

Comment [B29]: Separate references to "unreasonable risk" have been eliminated under this bill; conforming change.

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a ~~regulation~~ rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a ~~regulation~~ rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a ~~regulation~~ rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

"(5) EXEMPTIONS.—

"(A) IN GENERAL.—The Administrator may exempt 1 or more uses of a chemical substance from any restriction in a ~~regulation~~ rule promulgated under paragraph (1) if the Administrator determines that—

"(i) the ~~regulation~~ rule cannot be complied with, without—

"(I) harming national security;

"(II) causing significant disruption in the national economy due to the lack of availability of a chemical substance; or

"(III) interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or

"(ii) the use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to ~~human~~ health, the environment, or public safety.

"(B) EXEMPTION ANALYSIS.—In proposing a ~~regulation~~ rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall make publicly available any analysis conducted under this paragraph to assess the need for the exemption.

"(C) STATEMENT REQUIRED.—In making final a ~~regulation~~ rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall include a statement describing how the analysis considered under subparagraph (B) was taken into account.

"(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—In determining whether an exemption should be granted under this paragraph for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more technically and economically feasible alternatives to the chemical substance most likely to be used in place of the chemical substance under the ~~intended or reasonably anticipated~~ conditions of use if the ~~regulation~~ rule is promulgated.

"(E) CONDITIONS.—As part of a ~~regulation~~ rule promulgated under paragraph (1), the Administrator shall include conditions in any exemption established under this paragraph, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect ~~human~~ health and the environment while achieving the purposes of the exemption.

"(F) DURATION.—

"(i) IN GENERAL.—The Administrator shall establish, as part of a ~~regulation~~ rule under paragraph (1) that contains an exemption under this paragraph, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis.

"(ii) AUTHORITY OF ADMINISTRATOR.—The Administrator, by ~~regulation~~rule, may extend, modify, or eliminate the exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or is no longer necessary.

"(iii) CONSIDERATIONS.—

"(I) IN GENERAL.—Subject to subclause (II), the Administrator shall issue exemptions and establish time periods by considering factors determined by the Administrator to be relevant to the goals of fostering innovation and the development of alternatives that meet the safety standard.

"(II) LIMITATION.—Any renewal of an exemption in the case of a ~~regulation~~ rule requiring the ban or phase-out of a chemical substance shall not exceed 5 years.

"(e) Immediate Effect.—The Administrator may declare a proposed ~~regulation~~ rule under subsection (d) to be effective on publication of the ~~regulation~~ rule in the Federal Register and until the effective date of final action taken respecting the ~~regulation~~rule, if—

"(1) the Administrator determines that—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to the proposed ~~regulation~~ rule or any combination of those activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before the effective date; and

"(B) making the proposed ~~regulation~~ rule so effective is necessary to protect the public interest; and

"(2) in the case of a proposed ~~regulation~~ rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under paragraph (1)(A), a court has granted relief in an action under section 7 with respect to that risk associated with the chemical substance or mixture.

"(f) Final Agency Action.—Under this section—

"(1) a safety determination, and the associated safety assessment, for a chemical substance that the Administrator determines under subsection (c) meets the safety standard, shall be considered to be a final agency action, effective beginning on the date of issuance of the final safety determination; and

"(2) a final ~~regulation~~ rule promulgated under subsection (d), and the associated safety assessment and safety determination that a chemical substance does not meet the safety standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final ~~regulation~~rule.";

(4) in subsection (~~gh~~) (as redesignated by paragraph (2))—

(A) by striking paragraph (4); and

(B) by redesignating paragraph (5) as paragraph (4)~~; and~~

~~(5) by adding at the end the following:~~

~~"(j) Prior Actions.—Nothing in this section requires the Administrator to modify or withdraw any regulation or order promulgated pursuant to this section, as in effect on the day before the date of enactment of the Chemical Safety Improvement Act.".~~

Formatted: Indent: Left: 0.67"

Comment [B30]: Moved to section 26(h)

SEC. 9. IMMINENT HAZARDS.

Section 7 of the Toxic Substances Control Act (15 U.S.C. 2606) is amended—

(1) by striking subsection (a) and inserting the following:

"(a) Civil Actions.—

"(1) IN GENERAL.—The Administrator may commence a civil action in an appropriate United States district court for—

"(A) seizure of an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture;

"(B) relief (as authorized by subsection (b)) against any person that manufactures, processes, distributes in commerce, uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing the chemical substance or

mixture; or

"(C) both seizure described in subparagraph (A) and relief described in subparagraph (B).

"(2) ~~REGULATION~~RULE, ORDER, OR OTHER PROCEEDING.—A civil action may be commenced under this paragraph, notwithstanding—

"(A) the existence of—

"(i) a decision by the Administrator under section 4A, 5(d)(3), or 6(c)(1); or

"(ii) a ~~regulation~~rule, testing consent agreement, or order under section 4, 5(d)(4), 6(d), or 6(h); or

"(B) the pendency of any administrative or judicial proceeding under any provision of this Act.";

(2) in subsection (d), by striking "section 6(a)" and inserting "section 6(c)"; and

(3) in subsection (f), in the first sentence, by striking "and unreasonable".

SEC. 10. INFORMATION COLLECTION AND REPORTING.

Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amended—

(1) in subsection (a)—

(A) in paragraph (3)(A)(ii)(I)—

(i) by striking "5(b)(4)" and inserting "5";

(ii) by inserting "section 4 or" after "in effect under"; and

(iii) by striking "5(e)," and inserting "5(d)(4);"; and

(B) by adding at the end the following:

"(4) ~~REGULATIONS~~RULES.—

"(A) DEADLINE.—

"(i) IN GENERAL.—Not later than 2 years after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall promulgate ~~regulations~~ rules requiring the maintenance of records and the reporting of information known or reasonably ascertainable by the person making the report, including ~~regulations~~ rules requiring processors to report information, so that the Administrator has the information necessary to carry out sections 4 and 6.

"(ii) MODIFICATION OF PRIOR ~~REGULATIONS~~RULES.—In carrying out this subparagraph, the Administrator may modify, as appropriate, ~~regulations~~ rules promulgated before the date of enactment of the Chemical Safety Improvement Act.

"(B) CONTENTS.—The ~~regulations~~ rules promulgated pursuant to subparagraph (A)—

"(i) may impose different reporting and recordkeeping requirements on

Comment [B31]: Clarify that requirements include recordkeeping

manufacturers and processors; and

"(ii) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported; and

~~"(iii) shall apply only in cases in which the Administrator determines that the submission of reports would assist in the effective implementation of this Act~~.

"(C) ADMINISTRATION.—In implementing the reporting and recordkeeping requirements under this paragraph, the Administrator shall take measures—

"(i) to limit the potential for duplication in reporting requirements;

"(ii) to minimize the impact of the ~~regulations~~ rules on small manufacturers and processors; and

"(iii) to apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.

"(5) GUIDANCE.—The Administrator shall develop guidance relating to the information required to be reported under the ~~regulations~~ rules promulgated under this subsection.";

(2) in subsection (b), by adding at the end the following:

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Chemical Safety Improvement Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

"(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

"(I) cement, Portland, chemicals, CAS No. 65997–15–1;

"(II) cement, alumina, chemicals, CAS No. 65997–16–2;

"(III) glass, oxide, chemicals, CAS No. 65997–17–3;

"(IV) frits, chemicals, CAS No. 65997–18–4;

"(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

"(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature

conventions, the Administrator shall—

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

"(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) ~~REGULATIONS~~RULES.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, the Administrator, by ~~regulation~~rule, shall require manufacturers and processors to notify the Administrator, by not later than 180 days after the date of promulgation of the ~~regulation~~rule, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Chemical Safety Improvement Act.

"(ii) ACTIVE SUBSTANCES.—The Administrator shall, pursuant to paragraph (5)(A), designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—The ~~regulation~~ rule promulgated by the Administrator pursuant to subparagraph (A) shall require—

"(i) the Administrator to maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

"(ii) a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

"(iii) the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C).

"(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a ~~regulation~~ rule that establishes a plan to review all

claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are notified pursuant to subparagraph (A) or identified as active substances under subsection (f)(1).

"(D) REQUIREMENTS OF REVIEW PLAN.—The review plan under subparagraph (C) shall—

"(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

"(ii) require the Administrator, in accordance with section 14—

"(I) to review each substantiation—

"(aa) submitted pursuant to clause (i) to determine if the claim warrants protection from disclosure; and

"(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

"(II) approve, modify, or deny each claim; and

"(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(iii) encourage manufacturers or processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

"(E) TIMELINE FOR COMPLETION OF REVIEWS.—

"(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

"(ii) CONSIDERATIONS.—

"(I) IN GENERAL.—The Administrator may extend the deadline for

completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of applicable claims needing review and the available resources.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of reviews to be completed over the course of implementation of the plan.

~~"(F) LIMITATION.—The specific identity of any chemical substance that is not on the confidential portion of the list published under paragraph (1) or subsequently added to the confidential portion of the list pursuant to section 14 shall not be eligible for protection from disclosure.~~

Comment [B32]: Moved, modified and consolidated under new paragraphs (8) and (9) below.

~~"(G) CERTIFICATION.—The regulation under this subsection shall require a manufacturer or processor—~~

~~"(i) to certify the accuracy of each report of the manufacturer or processor carried out under the regulation; and~~

~~"(ii) to retain a record supporting that certification for a period of 5 years beginning on the last day of the submission period.~~

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

"(A) IN GENERAL.—The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).

"(B) UPDATE.—The Administrator shall update the list of chemical substances designated as active substances as soon as practicable after the date of publication of the most recent data reported under—

"(i) part 711 of title 40, Code of Federal Regulations (or successor regulations); and

"(ii) the regulations promulgated pursuant to subsection (a)(4).

"(C) CHANGE TO ACTIVE STATUS.—

"(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

"(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—

~~"(I) IN GENERAL.—~~If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the inactive substance as confidential, the person shall—

Formatted: Indent: Left: 1"

"(I~~aa~~) in the notice submitted under clause (i), assert the claim; and

"(II~~bb~~) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

~~"(II) LIMITATION.—The specific identity of any inactive substance that is not on the confidential portion of the list published under paragraph (1) or subsequently added to the confidential portion of the list pursuant to section 14 shall not be eligible for protection from disclosure.~~

Comment [B33]: Moved, modified and consolidated in paragraphs (8) and (9) below.

"(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

"(I) designate the applicable chemical substance as an active substance;

"(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific identity of the chemical substance and approve, modify, or deny the claim;

"(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of not less than 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines to be necessary.

"(D) CATEGORY STATUS.—The list of inactive substances shall not be considered to be a category for purposes of section 26(c).

"(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the ~~regulation~~ rule required under this subsection, the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (or successor regulations), during the reporting period that most closely preceded the date of enactment of the Chemical Safety Improvement Act, as the ~~initial~~interim list of active substances for the purposes of section 4A.

"(7) PUBLIC PARTICIPATION.—Subject to this subsection, the Administrator shall make available to the public—

"(A) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—

"(i) an active substance; or

"(ii) an inactive substance;

"(B) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list

published under paragraph (1) for which a claim of confidentiality was received and approved by the Administrator pursuant to section 14; and

"(C) subject to section 14(g), the specific identity of any active substance for which—

"(i) no claim of protection against disclosure of the specific identity of the active substance pursuant to this subsection was received;

"(ii) a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or

"(iii) the time period for protection against disclosure of the specific identity of the active substance has expired.";

"(8) LIMITATION.—No person may assert a new claim under this subsection for protection from disclosure of a specific identity of any active or inactive chemical substance for which a notice is received under paragraph (4)(A)(i) or paragraph (5)(B)(i) that is not on the confidential portion of the list published under paragraph (1).

"(9) CERTIFICATION.—Under the rule promulgated under this subsection, manufacturers and processors shall be required—

"(A) to certify that each report the manufacturer or processor submits complies with the requirements of the rule, and that any confidentiality claims are true and correct; and

"(B) to retain a record supporting the certification for a period of 5 years beginning on the last day of the submission period.";

(3) in subsection (e)—

(A) by striking "Any person" and inserting the following:

"(1) IN GENERAL.—Any person"; and

(B) by adding at the end the following:

"(2) APPLICABILITY.—Any person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of injury to ~~human~~ health and the environment."; and

(4) in subsection (f), by striking "For purposes of this section, the" and inserting the following: "In this section:

"(1) ACTIVE SUBSTANCE.—The term 'active substance' means a chemical substance—

"(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Chemical Safety Improvement Act;

"(B) that is added to the list published under subsection (b)(1) after that date of enactment; or

"(C) for which a notice is received under subsection (b)(5)(C).

"(2) INACTIVE SUBSTANCE.—The term 'inactive substance' means a chemical substance

Comment [B34]: Clarifies the application of these provisions to the entire subsection.

Formatted: Indent: Left: 0.33"

Formatted: Indent: Left: 0.5"

on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).

"(3) MANUFACTURE; PROCESS.—The".

SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.

Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the first sentence—

(i) by striking "presents or will present an unreasonable risk to health or the environment" and inserting "does not meet the safety standard"; and

(ii) by striking "such risk" the first place it appears and inserting "the risk posed by the substance or mixture";

(B) in paragraph (2), in the matter following subparagraph (B), by striking "section 6 or 7" and inserting "section 6(d) or section 7"; and

(C) in paragraph (3), by striking "section 6 or 7" and inserting "section 6(d) or 7"; and

(2) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

SEC. 12. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA.

Section 10 of the Toxic Substances Control Act (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".

SEC. 13. EXPORTS.

Section 12 of the Toxic Substances Control Act (15 U.S.C. 2611) is amended—

(1) in subsection (a), by striking paragraph (2) and inserting the following:

"(2) EXCEPTION.—Paragraph (1) shall not apply to any chemical substance that the Administrator determines—

"(A) under section 5 is not likely to meet the safety standard; or

"(B) under section 6 does not meet the safety standard.

"(3) WAIVERS.—For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—

"(A) determine that paragraph (1) shall not apply to the mixture or article; or

"(B) establish a threshold concentration in a mixture or article at which paragraph (1) shall not apply.

"(4) TESTING.—The Administrator may require testing under section 4 of any chemical

substance or mixture exempted from this Act under paragraph (1) for the purpose of determining whether the chemical substance or mixture ~~presents an unreasonable risk of harm to human health~~meets the safety standard within the United States ~~or to the environment of the United States~~.";

Comment [B35]: Conforming change.

(2) by striking subsection (b) and inserting the following:

"(b) Notice.—

"(1) IN GENERAL.—A person shall notify the Administrator that the person is exporting or intends to export to a foreign country—

"(A) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 5 is not likely to meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(B) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 6 does not meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(C) a chemical substance for which the United States is obligated by treaty to provide export notification;

"(D) a chemical substance or mixture subject to a prohibition or other restriction pursuant to a ~~regulation~~rule, order, or consent agreement in effect under this Act; or

"(E) a chemical substance or mixture for which the submission of information is required under section 4.

"(2) ~~REGULATIONS~~RULES.—

"(A) IN GENERAL.—The Administrator shall promulgate ~~regulations~~ rules to carry out paragraph (1).

"(B) CONTENTS.—The ~~regulations~~ rules promulgated pursuant to subparagraph (A) shall—

"(i) include such exemptions as the Administrator determines to be appropriate, which may include exemptions identified under section 5(h); and

"(ii) indicate whether, or to what extent, the ~~regulations~~ rules apply to articles containing a chemical substance or mixture described in paragraph (1).

"(3) NOTIFICATION.—The Administrator shall submit to the government of each country to which a chemical substance or mixture is exported—

"(A) for a chemical substance or mixture described in subparagraph (A), (B), or (D) of paragraph (1), a notice of the determination, ~~regulation~~rule, order, consent agreement, requirement, or designation;

"(B) for a chemical substance described in paragraph (1)(C), a notice that satisfies the obligation of the United States under the applicable treaty; and

"(C) for a chemical substance or mixture described in paragraph (1)(E), a notice of

availability of the information on the chemical substance or mixture submitted to the Administrator."; and

(3) in subsection (c)—

(A) by striking paragraph (3); and

(B) by redesignating paragraphs (4) through (6) as paragraphs (3) through (5), respectively.

SEC. 14. IMPORTS.

Section 13 of the Toxic Substances Control Act (15 U.S.C. 2612) is amended to read as follows:

"SEC. 13. IMPORTS.

"(a) Refusal of Entry.—

"(1) IN GENERAL.—The Secretary of Homeland Security shall refuse entry into the customs territory of the United States (as defined in general note 2 to the Harmonized Tariff Schedule of the United States) any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry, if—

"(A) the Administrator—

"(i) has determined under section 6(c) that the chemical substance or mixture does not meet the safety standard; and

"(ii) has promulgated a ~~regulation~~ rule pursuant to section 6(d) banning the chemical substance or mixture, as of the effective date of the ~~regulation~~rule;

"(B) the chemical substance—

"(i) is not included on the list under section 8(b)(1); and

"(ii) is not exempt from any requirement to be included on that list by this title or a ~~regulation~~ rule promulgated by the Administrator pursuant to this title; or

"(C) the chemical substance, mixture, or any article containing the chemical substance or mixture is offered for entry in violation of—

"(i) a ~~regulation~~rule, consent agreement, or order in effect under this Act; or

"(ii) an order issued in a civil action brought under section 7 or title IV.

"(2) PROCEDURE.—

"(A) IN GENERAL.—Subject to subparagraph (B), if a chemical substance, mixture, or article containing a chemical substance or mixture is refused entry under paragraph (1), the Secretary of Homeland Security—

"(i) shall notify the consignee of the entry of the refusal;

"(ii) shall not release the chemical substance or mixture to the consignee; and

"(iii) shall cause the disposal or storage of the chemical substance or mixture under such ~~regulations~~ rules as the Secretary may prescribe, if the chemical

substance or mixture has not been exported by the consignee during the 90-day period beginning on the date of receipt of the notice of the refused entry.

"(B) EXCEPTION.—

"(i) IN GENERAL.—The Secretary of Homeland Security, pending a review by the Administrator, may release to the consignee the chemical substance or mixture if the consignee—

"(I) executes a bond for the amount of the full invoice of the chemical substance or mixture (as set forth in the customs entry); and

"(II) pays a duty on the chemical substance or mixture.

"(ii) ADMINISTRATION.—If a consignee fails to return a chemical substance or mixture released to that consignee under clause (i) for any cause to the custody of the Secretary of Homeland Security on demand, the consignee shall be liable to the United States for liquidated damages equal to the full amount of the bond executed under clause (i)(I).

"(C) STORAGE.—All charges for storage, cartage, and labor on or for the disposal of a chemical substance or mixture that is refused entry or released under this subsection shall be paid by the owner or consignee, and a default on that payment shall constitute a lien against any future entry made by the owner or consignee.

"(b) Certification.—

"(1) IN GENERAL.—A person offering a chemical substance or mixture subject to this Act for entry into the customs territory of the United States shall certify to the Secretary of Homeland Security that—

"(A) after reasonable inquiry and to the best knowledge and belief of the person, the chemical substance or mixture is in compliance with any applicable ~~regulation~~rule, consent agreement, or order under section 5 or 6; and

"(B) the chemical substance—

"(i) is included on the list under section 8(b)(1); or

"(ii) is exempt from any requirement to be included on that list by this title or a ~~regulation~~ rule promulgated by the Administrator pursuant to this title.

"(2) ARTICLES.—

"(A) IN GENERAL.—The Administrator, by ~~regulation~~rule, may require certification under paragraph (1) for an article containing a chemical substance or mixture that is subject to ~~regulation~~ rule under section 5 or 6.

"(B) REQUIREMENT.—The ~~regulation~~ rule under subparagraph (A) shall identify, with reasonable specificity, the types of articles, including parts or components of articles, that will be subject to the certification requirement.

"(C) FACTORS FOR CONSIDERATION.—In determining the need for and content of a certification ~~regulation~~ rule under this paragraph, the Administrator shall take into consideration—

"(i) the utility of the certification to enforcement of the applicable ~~regulation~~rule, consent agreement, or order under section 5 or 6;

"(ii) the contribution of imported articles to the potential risk presented by exposure to the chemical substance or mixture subject to ~~regulation~~ rule under section 5 or 6;

"(iii) the impact on commerce and potential for the certification to impede or disrupt import of articles;

"(iv) the frequency or duration of the certification requirement; and

"(v) specification of the concentration of a chemical substance in an article that would subject the article to the certification requirement.

"(3) REASONABLE INQUIRY.—

"(A) IN GENERAL.—For purposes of a certification under paragraph (1), reasonable inquiry shall include good faith reliance by an importer on—

"(i) a safety data sheet or similar declaration provided by a supplier that documents the specific identity of the chemical substance or the specific identities of all chemical substances in a mixture; or

"(ii) for chemical substances or mixtures claimed by the supplier as confidential, or not otherwise disclosed by the supplier, a certification by the supplier that the imported chemical substance or mixture satisfies the applicable certification requirements under paragraph (1).

"(B) ARTICLES.—For purposes of a certification under paragraph (2), reasonable inquiry shall include good faith reliance by an importer on a certification by the supplier that the imported article satisfies the applicable certification requirements in a ~~regulation~~ rule promulgated pursuant to paragraph (2).

"(4) INFORMATION REGARDING IDENTITY.—For purposes of this subsection, the Administrator shall provide publicly accessible information regarding the identity of a chemical substance or mixture subject to ~~regulation~~ rule under this Act that would be readily understood in import transactions.

"(c) Notice.—A person offering a chemical substance for entry into the customs territory of the United States shall notify the Secretary of Homeland Security if—

"(1) the chemical substance or chemical substance in a mixture is a high-priority substance;

"(2) the chemical substance or chemical substance in a mixture is 1 for which the United States is obligated to provide export notification by treaty; or

"(3) the chemical substance or chemical substance in a mixture—

"(A) is the subject of a safety assessment and safety determination conducted pursuant to section 6; and

"(B) has been found not to meet the safety standard.

"(d) ~~Regulations~~Rules.—

"(1) IN GENERAL.—The Secretary of Homeland Security, after consultation with the Administrator, shall promulgate ~~regulations~~ rules to carry out this section.

"(2) APPLICATION.—The ~~regulations~~ rules under paragraph (1) may modify the application of any requirement of this section, as appropriate for the efficient and effective implementation of this Act.".

SEC. 15. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

Comment [B36]: Ensures subsection (b) information must also meet FOIA exceptions.

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer and specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

"(7) Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if—

"(A) the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5; and

"(B) the claim—

"(i) is not subject to an exception under subsection (e); or

Comment [B37]: Clarifying change
Formatted: Indent: First line: 0.33"

"(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection ~~(e)~~, (f)(2), or (g).

"(c) Information Not Protected From Disclosure.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

"(1) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

"(A) IN GENERAL.—Subject to subparagraph (B), subsection (a) does not prohibit the disclosure of—

"(i) any health and safety study that is submitted under this Act with respect to—

"(I) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

"(II) any chemical substance or mixture for which—

"(aa) testing is required under section 4; or

"(bb) a notification is required under section 5; or

"(ii) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in subclause (I) or (II) of clause (i).

"(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph authorizes the release of any information that discloses—

"(i) a process used in the manufacturing or processing of a chemical substance or mixture; or

"(ii) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

"(2) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(3) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

"(A) For information submitted after the date of enactment of the Chemical Safety Improvement Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

"(B) A safety assessment developed, or a safety determination made, under section 6.

"(C) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in

ranges.

"(D) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

"(4) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is otherwise eligible for protection under this section and contained in a submission of information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

~~"(5) LIMITATION.—Except as provided in paragraph (1)(B), the specific identity of any chemical substance that is not on the confidential portion of the list published under section 8(b)(1) or subsequently added to the confidential portion of the list pursuant to this section shall not be eligible for protection from disclosure.~~

Comment [B38]: Addressed in subsection (d) clarifying that publicly available information cannot be claimed confidential.

"(6) BAN OR PHASE-OUT.—If the Administrator promulgates a ~~regulation~~ rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance—

"(A) any protection from disclosure provided under this section with respect to information relating to the chemical substance shall no longer apply; and

"(B) the Administrator promptly shall make the information public.

"(d) Requirements for Confidentiality Claims.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such ~~regulations~~ rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the ~~chemical identity~~information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law ~~in connection with 1 or more uses subject to this Act~~;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the conditions that—

"(i) the generic name shall—

"(I) conform with guidance prescribed by the Administrator under paragraph (3)(A); and

"(II) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(aa) that are considered to be confidential; and

"(bb) the disclosure of which would be likely to harm the competitive position of the person.

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

Formatted: Indent: Left: 0.5"

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in paragraphs (1) through (7) of subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the ~~regulations~~ rules promulgated and guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the information that has been submitted is true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a) shall be disclosed if—

"(1) the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of ~~human~~ health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) the Administrator determines that disclosure is necessary to protect ~~human~~ health or the environment;

"(4) the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, if—

"(A) 1 or more applicable agreements with the Administrator that conform with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; and

"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;

"(5) a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement shall conform with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable

basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee;

~~"(9) the information is publicly available; or~~ Comment [B39]: Addressed in subsection (d)

"(9~~10~~) the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION PROTECTED FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information that meets the requirements of subsection (d) for a period of 10 years, unless, prior to the expiration of the period—

"(i) an affected person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in subsection (g)(2).

"(B) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph (A), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph (A), a person reasserting the relevant claim shall submit to the Administrator a statement substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—

"(aa) review the request;

"(bb) make a determination regarding whether the information for which the request is made continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of not more than 10 years; or

"(BB) deny the claim.

"(C) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph (B), if the Administrator determines that the relevant statement under subparagraph (B)(ii)(I)—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection against disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Chemical Safety Improvement Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating ~~regulations~~ rules pursuant to section 6(d), subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d).

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection

from disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Chemical Safety Improvement Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) as necessary to comply with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(ii) if information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met; or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator on expiration of the period for appeal under subsection (g)(3), that has expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

"(B) DENIAL OR MODIFICATION.—

"(i) IN GENERAL.—Except as provided in subsections (c) and (f), the Administrator shall deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).

"(ii) REASONS FOR DENIAL OR MODIFICATION.—The Administrator shall provide to a person that has submitted a claim described in clause (i) a written statement of the reasons for the denial or modification of the claim.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection (b)(7), review all claims under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim under paragraph (1), the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

"(B) RELEASE OF INFORMATION.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

"(ii) EXCEPTIONS.—

"(I) IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to ~~human~~ health or the environment, in which case no prior

notification shall be necessary.

"(II) NO NOTIFICATION.—For information under paragraph (1), (2), (6), (7), or (9), ~~or (10)~~ of subsection (e), no prior notification shall be necessary.

Comment [B40]: No longer necessary with the clarification that publicly available information cannot be claimed confidential.

"(3) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(4) ADMINISTRATION.—In carrying out this subsection, the Administrator shall use the procedures described in part 2 of title 40, Code of Federal Regulations (or successor regulations).

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information submitted to the Administrator under this Act before the date of enactment of the Chemical Safety Improvement Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

"(2) PRIOR ACTIONS.—Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such ~~regulations~~ rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Chemical Safety Improvement Act.".

SEC. 16. PROHIBITED ACTS.

Section 15 of the Toxic Substances Control Act (15 U.S.C. 2614) is amended by striking paragraph (1) and inserting the following:

"(1) fail or refuse to comply with—

"(A) any ~~regulation~~ rule promulgated, consent agreement entered into, or order issued under section 4;

"(B) any requirement under section 5 or 6;

"(C) any ~~regulation~~ rule promulgated, consent agreement entered into, or order issued under section 5 or 6; or

"(D) any requirement of, or any ~~regulation~~ rule promulgated or order issued pursuant to title II;".

SEC. 17. PENALTIES.

Section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) is amended—

(1) in subsection (a)(1)—

(A) in the first sentence—

(i) by inserting "this Act or a ~~regulation~~ rule or order promulgated or issued pursuant to this Act, including" after "a provision of"; and

(ii) by striking "$25,000" and inserting "$37,500"; and

(B) in the second sentence, by striking" violation of section 15 or 409" and inserting "violation of this Act"; and

(2) in subsection (b)—

(A) by striking "Any person who" and inserting the following:

"(1) IN GENERAL.—Any person that";

(B) by striking "section 15 or 409" and inserting "this Act";

(C) by striking "$25,000" and inserting "$50,000"; and

(D) by adding at the end the following:

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of this Act, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

"(B) ORGANIZATIONS ~~AND ENTITIES~~.—An ~~[~~organization ~~or entity~~~~]~~ that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation.

Comment [B41]: Changes conforms this provision to other federal law.

"(3) KNOWLEDGE OF IMMINENT DANGER OR INJURY.—For purposes of determining whether a defendant knew that the violation placed another individual in imminent danger of death or serious bodily injury—

"(A) the defendant shall be responsible only for actual awareness or actual belief possessed; and

"(B) knowledge possessed by an~~other~~ individual may not be attributed to the defendant.".

SEC. 18. ~~PREEMPTION~~ STATE-FEDERAL RELATIONSHIP.

Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following:

"(a) In General.—

"(1) ESTABLISHMENT OR ENFORCEMENT.—Except as provided in subsections (c) and (d) **and subject to paragraphs (2) and (3)**, no State or political subdivision of a State may establish or continue to enforce ~~[~~any of the following:~~[Legis. Counsel note: this phrase and the colon have been inserted here and in subsection (b) to comply with formatting conventions regarding the use below of provisions with headers.]]~~

"(A) TESTING AND INFORMATION COLLECTION.—A statute or administrative action to require ~~for~~ the development of information on a chemical substance or category of substances that is reasonably likely to produce the same information required under section 4, 5, or 6 in—

"(i) a rule promulgated by the Administrator;

"(ii) a testing consent agreement entered into by the Administrator; or

"(iii) an order issued by the Administrator.

"(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

"(i) ~~for a substance~~ found to meet the safety standard and consistent with the scope of the determination made under section 6; ~~[~~or~~]~~

"(ii) ~~for a substance~~ found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

"(C) SIGNIFICANT NEW USE.—A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

~~"(2) EFFECTIVE DATE FOR SCOPE OF CERTAIN PREEMPTION.—Under this subsection, Federal preemption **provided under paragraph (1)(B)** of State statutes and administrative actions applicable to specific substances shall be consistent with the scope of the **apply only to the uses or conditions of use of such substances that are included in the scope of the safety** determination made by the Administrator and **for the substance, and of any rule the Administrator promulgates pursuant to section 6(d).**~~

Comment [B42]: Moved to new subsection (c) below

"(3) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of State statutes and administrative actions applicable to specific substances shall not occur until the ~~date of the Administrator's determination that the substance meets the safety standard or until the date on which compliance with the rule issued under section 6(d) is required.~~ **effective date of the applicable action described in paragraph (1) taken by the Administrator.**

"(b) New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions.—Except as provided in subsections (c) and (d), no State or political subdivision of a State may establish (after the date of enactment of the Chemical Safety Improvement Act) **a**~~[any of the following:]~~

~~"(1) High priority.—A~~ statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance ~~identified~~ **designated** under section 4A, as of the date on which the Administrator commences a safety assessment under section 6.

~~"(2) Low priority.—A statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a low-priority substance identified under section 4A, as of the date on which the Administrator designates the substance as a low priority.~~

"(c) ~~EFFECTIVE DATE FOR~~ SCOPE OF PREEMPTION.— Federal preemption **under** subsections (a) and (b) of State statutes and administrative actions applicable to specific substances shall ~~be consistent with the scope of the~~ **apply only to the** chemical substances or category of substances subject to a rule or order, the **uses or conditions of use of such substances that are** identified by the Administrator as subject to review in a safety assessment and **included in the scope of the safety** determination made by the Administrator ~~and~~ **for the substance,** or **of any rule the Administrator promulgates pursuant to section 6(d).**

Comment [B43]: Modified to address scope of preemption under both (a) and (b).

"(d) Exceptions.—

"(1) ~~[IN GENERAL].—SUBSECTIONS~~ **IN GENERAL.—Subsections** (a) and (b) shall not apply to a ~~requirement, prohibition, or restriction~~ **statute or administrative action** of a State or a political subdivision of a State ~~that—[Legis. Counsel note: Generic header was added here and in paragraph (3) to ensure consistency with paragraph (2), which was given a header in client specs]~~ **applicable to a specific chemical substance that—**

"(A) is adopted under the authority of**, or authorized to comply with,** any other Federal law;

"(B) implements a reporting, monitoring, or **other** information collection ~~requirement~~ **obligation for the chemical substance** not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal ~~that—~~**, unless the~~~~at~~ **action taken by the State or political subdivision of a State—**

~~"(i) does not impose~~**"(i) imposes** a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii) ~~is not otherwise required by or inconsistent with an~~ **(I) is already required by ~~an action~~a decision by the Administrator under section 5 or 6;** or

Formatted: Font: Not Bold

"(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that are included in the scope of a safety determination pursuant to section 6 or the scope of a significant new use rule promulgated pursuant to section 5, ~~**the same specific human health or environmental concern as an action taken by the Administrator under section 5 or 6**~~ **but is inconsistent with the action of the Administrator; or**

"(III) would cause a violation of the applicable action by the Administrator under section 5 or 6.

"(2) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—Nothing in this Act, nor any amendment made by this Act, nor any regulation, ~~requirement,~~ standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any regulation, ~~requirement,~~ standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

"(A) is adopted **under the authority of,** or authorized to comply with**,** any other Federal law;

"(B) implements **a** reporting, monitoring, or **other** information collection ~~requirement~~ **obligation for the chemical substance** not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal ~~that does not impose~~**, unless the~~~~at~~ action taken by the State or political subdivision of a**

State—

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance ~~and is not otherwise required by or inconsistent with an~~ **; and**

"(ii)(I) is already required by ~~an action~~a decision by the Administrator under section 5 or 6; or

Formatted: Font: Not Bold

"(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that are included in the scope of a safety determination pursuant to section 6 or the scope of a significant new use rule promulgated pursuant to section 5, **~~the same specific human health or environmental concern as an action taken by the Administrator under section 5 or 6~~ but is inconsistent with the action of the Administrator; or**

"(III) would cause a violation of the applicable action by the Administrator under section 5 or 6.

"(3) APPLICABILITY TO CERTAIN RULES OR ORDERS.—Notwithstanding subsection (d)—[~~Rule of construction~~].—~~Nothing construction.—N~~

Formatted: Indent: Left: 0.5"

"(A) nothing in this section shall be construed as ~~requiring the Administrator to modify or withdraw, any rule or order under section 5 or 6 of this Act, or as~~ modifying the effect ~~of~~under this section, as in effect immediately ~~as enacted~~ prior to [insert the effective date of the Chemical Safety Improvement Act], of ~~on~~ any rule or order promulgated or issued under this Act prior to [insert the effective date of the Chemical Safety Improvement Act], and

Comment [B44]: Corrected typo

"(B) with respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 6 prior to [insert the effective date of the Chemical Safety Improvement Act], this section as enacted prior to [insert the effective date of the Chemical Safety Improvement Act] shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after [insert the effective date of the Chemical Safety Improvement Act], unless the latter rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under section 4A(b) or (c) or as an additional priority for safety assessment and safety determination under section 4A(d).

"(~~c~~d) Preservation of Certain State Law.—Nothing in this section shall be construed to preempt or otherwise affect any ~~warning requirement relating to consumer products or substances that is~~ **statute or administrative action** taken before January 1, 2015, under the authority of a State law, **that prohibits or** otherwise **restricts ~~chemical~~ manufacturing, processing, distribution in commerce, ~~or~~ use,** or disposal of a chemical substance. This subsection does not affect the relationship between state and federal law pursuant to any other federal law. ~~established pursuant to State law that was in effect on August 31, 2003, unless a rule, consent agreement, or order is promulgated under section 6 imposing a warning requirement, which shall preempt a chemical specific State warning requirement consistent with the scope of the Administrator's determination under section 6. January 1, 2015.~~

"(~~f~~e) State Waivers.—

"(1) IN GENERAL.—Upon application of a State or political subdivision of a State, the Administrator ~~may provide a waiver~~ **may**—

"(A) by rule, exempt from subsection (a) ~~and subsection (b)(1), regarding~~**, under such conditions as may be prescribed in the rule,** a statute or administrative action of that State or political subdivision of the State that relates to the effects **of,** or exposure to ~~any~~**, a** chemical substance under the ~~intended or reasonably anticipated~~ conditions of use **if** ~~if—~~

~~"(A)(i) the State or political subdivision of the State determines it cannot wait until the end of the period specified in the established schedule and deadline for the completion of a full safety assessment and determination established under section 3A; and~~

~~"(ii)~~ the Administrator determines that—

~~"(I)~~**"(i)** compelling State or local conditions warrant granting the waiver to protect ~~human~~ health or the environment;

~~"(II)~~**"(ii)** compliance with the proposed requirement of the State or political subdivision of the State ~~will~~ **would** not unduly burden interstate ~~and foreign~~ commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

~~"(III)~~**"(iii)** compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

~~"(IV)~~**"(iv)** based on the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is consistent with sound objective scientific practices, the weight of the evidence, and the best available science; **or**~~"(B)(i) the Administrator finds a safety assessment or determination has been unreasonably delayed; and~~

~~"(ii) the State certifies that—~~**"(B) exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the** ~~intended or reasonably intended~~ **conditions of use if the Administrator determines that—**

~~"(I)~~**"(i)** the State has a compelling local interest **that warrants granting the waiver** to protect ~~human~~ health or the environment;

~~"(II)~~**"(ii)** compliance with the proposed requirement of the State will not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

~~"(III)~~**"(iii)** compliance with the proposed requirement would not cause a violation of any applicable Federal law, rule, or order; and

~~"(IV)~~**"(iv)** the proposed requirement is grounded in reasonable scientific concern~~; or~~

~~"(C)(i) the State has contracted with the National Academy of Sciences to assess the hazard, use and exposure, and risk of a chemical substance;~~

~~"(ii) the report complies with the requirements of the Federal Advisory Committee Act Amendments of 1997; and~~

~~"(iii) based on the best available evidence described in the report of the National Academy of Sciences, the State establishes a requirement relating to the effects of or exposure to a chemical substance~~.

"(2) APPROVAL OF A STATE WAIVER REQUEST.—The Administrator shall grant or deny a waiver application—

"(A) not later than 180 days after the date on which an application under paragraph (1)(A) is submitted; and

"(B) not later than 90 days after the date on which an application under paragraph (1)(B) is submitted.

"(3) NOTICE AND COMMENT.—The application of a State or political subdivision of the State shall be subject to public notice and comment.

"(4) FINAL AGENCY ACTION.—The decision of the Administrator on the application of a State or political subdivision of the State shall be—

"(A) considered to be a final agency action; and

"(B) subject to judicial review.

"(5) DURATION OF WAIVERS.—A **waiver** ~~waiver—~~

~~"(A)~~ granted under paragraph **(1)(B)**~~(1)(A) shall remain in effect unless the waiver is found to be in conflict with a completed safety assessment and determination; and~~

~~"(B) granted under [subparagraph (B) or (C) of paragraph (2)]~~ shall remain in effect until **the later of—**

"(A) such time as the safety assessment and determination is completed**; and**

~~"(6) Judicial review.—~~**"(B) the date on which compliance with an applicable rule issued under section 6(d) is required.**

~~"(A) In general.—Not~~**"(6) JUDICIAL REVIEW.—Not** later than 60 days after the date on which the Administrator makes a determination on an application of a State or political subdivision of the State under **subparagraph (A) or (B) of** paragraph (1), any person may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.

~~"(B) Judicial review of prioritization screening decision.—Not later than 60 days after the date on which the Administrator makes a decision on a recommendation made under section 4A(c) to designate a chemical substance as a low priority, the Governor of a State or a State agency with responsibility for protecting health and the environment that submitted the recommendation, as applicable, may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.~~

"(7) SAVINGS.—

"(A) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION FOR CIVIL

RELIEF OR CRIMINAL CONDUCT.—Nothing in this Act, nor any amendment made by this Act, nor any regulation, requirement, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall be construed to preempt, displace, or supplant any state or Federal common law rights or any state or Federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.

"(~~i~~B) CLARIFICATION OF NO PREEMPTION.—Notwithstanding any other provision in this Act, nothing in this Act, nor any amendments made by this Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any state, maritime, or Federal common law or statutory theory.

Formatted: Indent: Left: 0.83"

"(~~B~~C) NO EFFECT ON PRIVATE REMEDIES.—

"(i) Nothing in this Act, nor any amendments made by this Act, nor any rules, regulations, requirements, safety assessments, safety determinations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.

"(ii) This Act does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, safety assessments, scientific assessments, or orders issued pursuant to this Act.".

SEC. 19. JUDICIAL REVIEW.

Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking "section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting "section 4(a), 5(d)~~(4)~~, 6(c), 6(d), 6(g) or 8 of this title, or title II or IV of this chapter"; and

Comment [B45]: Conforming changes

(ii) in subparagraph (B), by striking "an order issued under subparagraph (A) or (B) of section 6(b)(1)" and inserting ~~[~~"an ~~regulation~~ order issued under this title"~~promulgated pursuant to section 6(d)"]~~; and

(B) in paragraph (2), in the first sentence, by striking "paragraph (1)(A)" and inserting "paragraph (1)"; and

(C) by striking paragraph (3); and

(2) in subsection (c)(1)—

(A) in subparagraph (B)—

(i) in clause (i)—

(I) by striking "section 4(a), 5(b)(4), 6(a), or 6(e)" and inserting "section

4(a), 5(d)~~(4)~~, ~~or~~ 6(d), or 6(g)"; and

(II) by striking "evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;" and inserting "evidence (including any matter) in the rulemaking record, taken as a whole; and"; and

(ii) by striking clauses (ii) and (iii) and the matter following clause (iii) and inserting the following:

"(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the ~~regulation~~rule, except as part of the rulemaking record, taken as a whole."; and

[(B) by striking subparagraph (C).]

SEC. 20. CITIZENS' PETITIONS.

Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an order under section 4 or 5(d)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "an order under section 4 or 5(d)"; and

(B) in paragraph (4), by striking subparagraph (B) and inserting the following:

"(B) DE NOVO PROCEEDING.—

"(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to promulgate a ~~regulation~~ rule pursuant to section 4, 5~~(d)~~, 6~~(b), 6(c), 6(d)~~, or 8 or an order issued under section 4 or 5~~(d)~~, the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.

"(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a ~~regulation~~ rule or order under section 4, the information available to the Administrator is insufficient for the Administrator to perform an action described in section 4, 4A, 5 or 6(d);

"(bb) in the case of a petition to issue an order under section 5(d), there is a reasonable basis to conclude that the chemical substance is not likely to meet the safety standard;

"(cc) in the case of a petition to initiate a proceeding for the issuance of a ~~regulation~~ rule under section 6(d), there is a reasonable basis to conclude that the chemical substance will not meet the safety standard;

or

"(dd) in the case of a petition to initiate a proceeding for the issuance of a ~~regulation~~ rule under section 8, there is a reasonable basis to conclude that the ~~regulation~~ rule is necessary to protect ~~human~~ health or the environment or ensure that the chemical substance meets the safety standard ~~from an unreasonable risk of harm to human health or the environment.~~

Comment [B46]: Conforming change

"(II) DEFERMENT.—The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

"(aa) the extent of the risk to ~~human~~ health or the environment alleged by the petitioner is less than the extent of risks to ~~human~~ health or the environment with respect to which the Administrator is taking action under this Act; and

"(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.".

SEC. 21. EMPLOYMENT EFFECTS.

Section 24(b)(2)(B)(ii) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by striking "section 6(c)(3)," and inserting "the applicable requirements of this Act;".

SEC. 22. STUDIES.

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.

SEC. 23. ADMINISTRATION.

Section 26 ~~(e) of the Toxic Substances Control Act (15 U.S.C. 2625(e)) is amended~~ **of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—**

(1) by striking subsection (b) and inserting the following:

"(b) Fees.—

"(1) IN GENERAL.—The Administrator shall establish, not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, by rule—

"(A) the payment of 1 or more reasonable fees as a condition of submitting a notice or requesting an exemption under section 5;

"(B) the payment of 1 or more reasonable fees by a manufacturer or processor that—

"(i) is required to submits a notice pursuant to the rule promulgated under section 8(b)(4)(A)(i) identifying a chemical substance as active;

Comment [B47]: Clarifies fee trigger

"(ii) is required to submits a notice pursuant to section 8(b)(5)(BE)(i) changing the status of a chemical substance from inactive to active;

"(iii) is required to report information pursuant to the rules promulgated under section 8(a)(4); and

"(iv) manufactures or processes a chemical substance subject to a safety assessment and determination ~~**designated by the Administrator as a high-priority substance**~~ **pursuant to section** ~~6~~4A(~~b~~).

Comment [B48]: Clarifies fee trigger

"(2) UTILIZATION AND COLLECTION OF FEES.—The Administrator shall—

"(A) utilize the fees collected under paragraph (1) only to defray costs associated with the actions of the Administrator—

"(i) to collect, process, review, provide access to, and protect from disclosure (where appropriate) information on chemical substances under this Act;

"(ii) to review notices and **make determinations for chemical substances under section 5**(d)(1) and ~~(e)~~**(3) and impose any**~~d~~ **necessary restrictions under section 5(**d~~e~~**)(4);**

"(iii) to make prioritization decisions under section 4A;

"(iv) to conduct and complete safety assessments and determinations under section 6; and

"(v) to conduct any necessary rulemaking pursuant to section 6(d);

"(B) insofar as possible, collect the fees described in paragraph (1) in advance of conducting any fee-supported activity;

"(C) deposit the fees in the Fund established by paragraph (4)(A); and

"(D) not collect excess fees or retain a significant amount of unused fees.

"(3) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—In setting fees under this section, the Administrator shall—

"(A) take into account the cost to the Administrator of conducting the activities described in paragraph (2);

"(B) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

"(C) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to defray approximately 25 percent of the ~~**a portion of the**~~ **costs of conducting the activities identified in** ~~**that**~~ **paragraph** (2)(A)**, not to exceed** ~~**[___] percent of the cost of conducting the activities described in paragraph (2)(A)**~~$18 million, not including fees under subparagraph (E) of this paragraph**;**

Comment [B49]: Clarifies that cap on fees does not include fees to defray the full cost of assessment/determinations under section 4A(c).

"(D) ~~**establish appropriate criteria for manufacturers or processors that results in a proportionate assessment of fees**~~reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors**;**

"(E) for substances designated as additional priorities pursuant to section

4A(c~~d~~), establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the safety assessment and safety determination under section 6;

"(F) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) or subchapter III of chapter 5 of title 5, United States Code, ~~shall accrue~~ is applicable with respect to such meetings;

"(G) beginning with the fiscal year that is 3 years after the date of enactment of the Chemical Safety Improvement Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives, increase or decrease the fees established under paragraph (1) as necessary—

"(i) to ensure that funds deposited in the Fund are sufficient ~~and not more than reasonably necessary to defray the portion of the costs specified in subparagraph (C) of conducting~~ to conduct the activities identified in paragraph (2~~1~~)(A) and the full costs of safety assessments and determinations pursuant to subparagraph (B); and

Comment [B50]: Clarification

Formatted: Font: Not Bold

"(ii) to account for inflation~~; and~~

~~"(iii) to minimize, to the maximum extent practicable, shortfalls in or an accumulation of unused amounts in the Fund established by paragraph (4)(A);~~

"(H) adjust fees established under paragraph (1) as necessary to vary on account of differing circumstances, including reduced fees or waivers in appropriate circumstances, to reduce the burden on manufacturing or processing, remove barriers to innovation, or where the costs to the Administrator of collecting the fees exceed the fee revenue anticipated to be collected; and

"(I) if a notice submitted under section 5 is refused or subsequently withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

"(4) TSCA IMPLEMENTATION FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the 'TSCA Implementation Fund' (referred to in this subsection as the 'Fund'), consisting of—

"(i) such amounts as are deposited in the Fund under paragraph (2)(C); and

"(ii) any interest earned on the investment of amounts in the Fund; and

"(iii) any proceeds from the sale or redemption of investments held in the Fund.

"(B) CREDITING AND AVAILABILITY OF FEES.—

"(i) IN GENERAL.—Fees authorized under this section shall be collected and

available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation.

"(ii) REQUIREMENTS.—Fees collected under this section shall not—

"(I) be made available or obligated for any purpose other than to defray the costs of conducting the activities identified in paragraph (2)(A);

"(II) otherwise be available for any purpose other than implementation of this Act; and

"(III) so long as amounts in the Fund remain available, be subject to restrictions on expenditures applicable to the Federal government as a whole.

"(C) UNUSED FUNDS.—Amounts in the Fund not currently needed to carry out this ~~paragraph~~ subsection shall be—

"(i) maintained readily available or on deposit;

"(ii) invested in obligations of the United States or guaranteed by the United States; or

"(iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

"(D) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2015) of the Office of Pollution Prevention and Toxics of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for covered functions for fiscal year 2015 (excluding the amount of any fees appropriated for the fiscal year).

"(5) AUDITING.—

"(A) FINANCIAL STATEMENTS OF AGENCIES.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of an executive agency.

"(B) COMPONENTS.—The annual audit required under sections 3515(b) and 3521 of that title of the financial statements of activities under this subsection shall include an analysis of—

"(i) the fees collected under paragraph (1) and disbursed;

"(ii) compliance with the deadlines established in section 6 of this Act;

"(iii) the amounts budgeted, appropriated, collected from fees, and disbursed to meet the requirements of sections 4, 4A, 5, 6, 8, and 14, including the allocation of full time equivalent employees to each such section or activity; and

"(iv) the reasonableness of the allocation of the overhead ~~allocation of costs~~ associated with the conduct of the activities described in paragraph (~~2~~1)(A).

"(C) INSPECTOR GENERAL.—The Inspector General of the Environmental Protection Agency shall—

"(i) conduct the annual audit required under this subsection; and

"(ii) report the findings and recommendations of the audit to the Administrator and to the appropriate committees of Congress.

"(6) TERMINATION.—The authority provided by this section shall terminate at the conclusion of the fiscal year that is ~~[~~10~~/15]~~ years after the date of enactment of the Chemical Safety Improvement Act, unless otherwise reauthorized or modified by Congress."; ~~and~~

(2) in subsection (e), by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services"; and

(3) adding at the end the following:

"(h) Prior Actions.—Nothing in this Act requires the Administrator to modify or withdraw any rule or order promulgated or issued pursuant to this Act before the date of enactment of the Chemical Safety Improvement Act.".

.

SEC. 24. DEVELOPMENT AND EVALUATION OF TEST METHODS.

Section 27(a) of the Toxic Substances Control Act (15 U.S.C. 2626(a)) is amended in the first sentence by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

SEC. 25. STATE PROGRAMS.

Section 28 of the Toxic Substances Control Act (15 U.S.C. 2627) is amended—

(1) in subsection (b)(1)—

(A) in subparagraphs (A) through (D), by striking the comma at the end of each subparagraph and inserting a semicolon; and

(B) in subparagraph (E), by striking ", and" and inserting "; and"; and

(2) by striking subsections (c) and (d).

SEC. 26. AUTHORIZATION OF APPROPRIATIONS.

Section 29 of the Toxic Substances Control Act (15 U.S.C. 2628) is repealed.

SEC. 27. ANNUAL REPORT.

Section 30 of the Toxic Substances Control Act (15 U.S.C. 2629) is amended by striking paragraph (2) and inserting the following:

"(2)(A) the number of notices received during each year under section 5; and

"(B) the number of the notices described in subparagraph (A) for chemical substances subject to a ~~regulation~~rule, testing consent agreement, or order under section 4;".

SEC. 28. EFFECTIVE DATE.

Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601 note; Public Law 94–469) is amended by striking "Except as provided in section 4(f), this" and inserting "This".

WORKING DRAFT P February 27, 2015
Reflecting Changes to the September, 2014 Draft
Bold Text Reflects Changes from Original Text in September, 2014 Draft

Title: To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Chemical Safety Improvement Act".

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(a) of the Toxic Substances Control Act (15 U.S.C. 2601(a)) is amended—

~~(1) in paragraph (2)—~~

Formatted: Indent: Before: 0"

~~(A) by striking "injury" and inserting "harm"; and~~

Commented [B1]: Existing TSCA and sections of TSCA not amended by this Act use "injury." The change thus conforms the bill to existing term. Change reflected throughout the bill

~~(B) by striking "and" at the end;~~

~~(2) by redesignating paragraph (3) as paragraph (4); and~~

~~(3) by inserting after paragraph (2) the following:~~ in subsection (c)—

(1) by designating the existing paragraph as paragraph (1);

(2) by inserting at the end of paragraph (1) (as so redesignated), "as provided under this Act."; and

(3) by inserting at the end of paragraph (1) (as so redesignated), the following:

"(~~2~~3) It is the intent of Congress that reform of this Act in accordance with the amendments made by the Chemical Safety Improvement Act—

Commented [B2]: Properly places this text in the Intent of Congress subsection of section 2.

"(A) shall be administered in a manner that—

"(i) protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and

"(ii) ensures that appropriate information on chemical substances and mixtures is available to public health officials and first responders in the event of an emergency; and

"(B) shall not displace or supplant common law rights of action or remedies for civil relief~~, and~~".

Commented [B3]: Corrects typo

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) by redesignating paragraphs (7), (8), (9), (10) , (11), (12), (13), and (14) as paragraphs (79), (910), (101), (13), (174), (189), and (1920), ~~and (21),~~ respectively;

(2) by inserting after paragraph (6) the following:

~~"(7) INFORMATION.—The term 'information' means any qualitative, quantitative, or descriptive facts, data, analysis, or assessment related to chemical hazards, use, or exposure (including the nature and extent of exposure to a chemical substance), including from health and safety studies.~~

"(78) ~~INTENDED OR REASONABLY ANTICIPATED~~ CONDITIONS OF USE.—The term ~~'intended or reasonably anticipated~~ 'conditions of use' means the intended, known, or reasonably foreseeable circumstances the Administrator determines ~~are those under which~~ a chemical substance is ~~is intended, reasonably known, or reasonably anticipated to be~~ manufactured, processed, distributed in commerce, used, ~~and~~or disposed of.";

(3) by inserting after paragraph (101) (as so redesignated) the following:

"(121) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.—The term 'potentially exposed or susceptible population' means 1 or more groups—

"(A) of individuals within the general population who may be—

"(i) differentially exposed to chemical substances under the ~~intended or reasonably anticipated~~ conditions of use; or

"(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

"(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; and

(4) by inserting after paragraph (134) (as so redesignated) the following:

~~"(15) PUBLICLY AVAILABLE.—~~

~~"(A) IN GENERAL.—The term 'publicly available', with respect to information, means information that is—~~

~~"(i) generally accessible and available to the general public; or~~

~~"(ii) in the public domain.~~

~~"(B) INCLUSIONS.—The term 'publicly available', with respect to information, includes information that has been published in periodicals, books, print, an electronic format, or other media available for general distribution to any member of the public.~~

"(146) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the ~~intended or reasonably anticipated~~ conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.

"(157) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the ~~intended or reasonably anticipated~~ conditions of use.

"(178) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of

Commented [B4]: Redesignated as a result of two definitions struck below.

Commented [B5]: Definition not necessary

Commented [B6]: Modifications to the definition of intended use eliminate the need to make this clarification, throughout.

Commented [B7]: Definition not necessary

~~harm~~ injury to ~~human~~ health or the environment will result from exposure to a chemical substance under the ~~intended or reasonably anticipated~~ conditions of use, including no unreasonable risk of ~~harm~~ injury to—

Commented [B8]: Existing TSCA and sections of TSCA not amended by this Act use "health" rather than "human health." Change reflected throughout the bill.

"(A) the general population; or

"(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

The Toxic Substances Control Act is amended by inserting after section 3 (15 U.S.C. 2602) the following:

"SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

"(a) Definition of Guidance.—In this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.

"(b) Deadline.—Not later than 2 years after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.

"(c) Use of Science.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance on the use of science in making decisions under sections 4, 4A, 5, and 6.

"(2) GOAL.—A goal of the policies and procedures described in paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) REQUIREMENTS.—The policies, procedures, and guidance issued under this section shall describe the manner in which the Administrator shall ensure that —

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;

"(B) to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.

"(e) Review.—Not later than 5 years after the date of enactment of this section, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(1) review the adequacy of any policies, procedures, and guidance developed under this section, including animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this Act; and

"(2) after providing public notice and an opportunity for comment, revise the policies, procedures, and guidance if necessary to reflect new scientific developments or understandings.

"(f) Sources of Information.—In making any decision with respect to a chemical substance under section 4, 4A, 5, or 6, the Administrator shall take into consideration information relating to the hazards and exposures of a chemical substance under the ~~intended or reasonably anticipated~~ conditions of use that is reasonably available to the Administrator, including information that is—

"(1) submitted to the Administrator pursuant to any regulationrule, consent agreement, order, or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act, by—

Commented [B9]: Existing TSCA uses the term "rule". Change conformed throughout the bill

"(A) manufacturers or processors of a substance;

"(B) the public;

"(C) other Federal departments or agencies; or

"(D) the Governor of a State or a State agency with responsibility for protecting health or the environment;

"(2) submitted to a governmental entity in any jurisdiction pursuant to a governmental requirement relating to the protection of ~~human~~ health or the environment; or

"(3) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible by the Administrator.

"(g) Exposure Information.—If the Administrator obtains information related to exposures or releases of a chemical substance that may be prevented or reduced under another Federal law, including laws not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.

Commented [B10]: Inserted to ensure that exposure/release information obtained by Administrator is shared appropriately.

"(h) Testing of Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator shall establish policies and procedures for the testing of chemical substances or mixtures under section 4.

"(2) GOAL.—A goal of the policies and procedures established under paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) CONTENTS.—The policies and procedures established under paragraph (1) shall—

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential;

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations;

"(C) require the Administrator to consult with the Director of the National Institute for Occupational Safety and Health prior to prescribing epidemiologic studies of employees; and

"(D) prior to adopting a requirement for testing using vertebrate animals, require the Administrator to take into consideration, as appropriate and to the extent practicable, reasonably available—

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

"(iii) high-throughput screening methods and the prediction models of those methods; and

"(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.

"(4) TIERED TESTING.—

"(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.

"(B) SCREENING-LEVEL TESTS.—

"(i) IN GENERAL.—The screening-level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.

"(ii) USE.—Screening-level tests shall be used—

"(I) to screen chemical substances or mixtures for potential adverse effects; and

"(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.

"(C) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for safety assessments or safety determinations, the Administrator may require more advanced tests for potential ~~human~~ health or environmental effects or exposure potential.

"(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

"(i~~h~~) Safety Assessments and Safety Determinations.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(C) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall identify the substances subject to safety assessments and safety determinations to be completed that year.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(A) IN GENERAL.—The Administrator shall establish, by ~~regulation~~rule, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

"(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

"(C) MINIMUM REQUIREMENTS.—At a minimum, the policies and procedures under this paragraph shall—

"(i) describe—

"(I) the manner in which the Administrator will identify informational needs and seek that information from the public;

"(II) the information (including draft safety assessments) that may be submitted by interested individuals or entities, including States; and

"(III) the criteria by which that information will be evaluated;

"(ii) require the Administrator—

"(I)(aa) to define the scope of the safety assessment and determination to be conducted under section 6, including identify the hazards, exposures, ~~intended or reasonably anticipated~~ conditions of use, and potentially exposed and susceptible populations that the Administrator expects to consider in a safety assessment;

"(bb) to explain the basis for ~~those identifications~~the scope of the safety assessment and determination; and

"(cc) to accept comments regarding the ~~identifications~~scope of the safety assessment and determination; and

"(II)(aa) to identify the items described in subclause (I) that the Administrator has considered in the final safety assessment; and

"(bb) to explain the basis for the consideration of those items;

"(iii) describe the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the ~~intended or reasonably anticipated~~ conditions of use will be considered, and explain the basis for that consideration in the final safety assessment;

"(iv) require that each safety assessment and safety determination shall include—

"(I) a description of the weight of the scientific evidence of risk; and

"(II) a summary of the information regarding the impact on ~~human~~ health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies; ~~and~~

"(v) establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination; and

"(vi) when relevant information is provided to or otherwise made available to the Administrator, consider the extent of federal regulation under other federal laws.

"(D) GUIDANCE.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall develop guidance to assist interested persons in developing draft safety assessments and other information for submission to the Administrator, which may be considered at the discretion of the Administrator.

"(ii) REQUIREMENT.—The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing a draft assessment for consideration by the Administrator.

Commented [B11]: Modified to make clear that the scope of safety assessments and determinations is subject to notice and comment. Conforms to changes made in section 6(a).

Commented [B12]: Inserted to ensure that Administrator considers information made available regarding other federal regulation that may be applicable.

"(3) Articles.— If the Administrator intends to prohibit or otherwise restrict an article on the basis of a chemical substance contained in that article, the Administrator shall have evidence of significant exposure to the chemical substance from such article.

"(~~j~~i) Publicly Available Information.—Subject to section 14, the Administrator shall—

"(1) make publicly available a nontechnical summary, and the final version, of each safety assessment and safety determination;

"(2) provide public notice and an opportunity for comment on each proposed safety assessment and safety determination; and

"(3) make public in a final safety assessment and safety determination—

"(A) the list of studies considered by the Administrator in carrying out the safety assessment or safety determination; and

"(B) the list of policies, procedures, and guidance that were followed in carrying out the safety assessment or safety determination.

"(~~k~~j) Consultation With Science Advisory Committee on Chemicals.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish an advisory committee, to be known as the 'Science Advisory Committee on Chemicals' (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, on the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(5) RELATIONSHIP TO OTHER LAW.—All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).".

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking subsections (a), (b), (c), (d), and (g);

(2) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively;

(3) in subsection (f) (as so redesignated)—

(A) by striking "rule" each place it appears and inserting "~~regulation~~rule, testing

Commented [B13]: Provides a consistent regulatory basis for articles which may be affected by a safety assessment/determination and rule.

Formatted: Indent: Before: 0.17"

Commented [B14]: Expands membership of Advisory Committee

consent agreement, or order";

(B) by striking "under subsection (a)" each place it appears and inserting "under this subsection"; and

(C) in paragraph (1)(B), in the last sentence, by striking "rulemaking";

(4) in subsection (g) (as so redesignated)—

(A) in the first sentence, by striking "from cancer, gene mutations, or birth defects"; and

(B) by striking the last sentence; and

(5) by inserting before subsection (f) (as so redesignated) the following:

"(a) Development of New Information on Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section if the Administrator determines that the information is necessary—

"(A) to review a notice under section 5(d) or to perform a safety assessment or safety determination under section 6;

Commented [B15]: Clarifies scope of testing authority

"(B) to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4) or under a rule promulgated under section 6(d)(3);

Commented [B16]: Clarifies scope of testing authority

"(C) pursuant to section 12(a)(4); or

"(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

"(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.

"(B) PROHIBITION.—Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.

"(C) LIMITATION.—The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

"(3) FORM.—Subject to section 3A(h~~f~~), the Administrator may require the development of ~~test data and~~ information described in paragraph (1) or (2) by—

"(A) promulgating a ~~regulation~~rule;

"(B) entering into a testing consent agreement; or

"(C) issuing an order.

"(4) CONTENTS.—

"(A) IN GENERAL.—A ~~regulation~~rule, testing consent agreement, or order issued under this subsection shall include—

"(i) identification of the chemical substance or mixture for which testing is required;

"(ii) identification of the persons required to conduct the testing;

"(iii) test protocols and methodologies for the development of test data and information for the chemical substance or mixture, including specific reference to reliable nonanimal test procedures; and

"(iv) specification of the period within which individuals and entities required to conduct the testing shall submit to the Administrator the information developed in accordance with the procedures described in clause (iii).

"(B) CONSIDERATIONS.—In determining the procedures and period to be required under subparagraph (A), the Administrator shall take into consideration—

"(i) the relative costs of the various test protocols and methodologies that may be required; and

"(ii) the reasonably foreseeable availability of facilities and personnel required to perform the testing.

"(b) Statement of Need.—

"(1) IN GENERAL.—In promulgating a ~~regulation~~rule, entering into a testing consent agreement, or issuing an order for the development of additional information (including information on exposure or exposure potential) pursuant to this section, the Administrator shall—

"(A) identify the need intended to be met by the ~~regulation~~rule, agreement, or order;

"(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of vertebrate animals.

"(2) EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an order is warranted instead of promulgating a ~~regulation~~ rule or entering into a testing consent agreement.

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a description of—

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

"(ii) the extent to which the Administrator has obtained or attempted to obtain the information through voluntary submissions; and

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

"(I) animal-based studies; and

"(II) emerging methods and models; and

"(B) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) after providing an opportunity for public comment, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information ~~used in safety assessments and safety determinations under section 6~~under this title that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

Commented [B17]: Clarifies that strategic plan applies to entire title

"(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

Commented [B18]: Ensures strategic plan is referenced as test plans are developed

"(C) beginning on the date that is 5 years after the date of enactment of the Chemical Safety Improvement Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation; and

"(~~C~~D) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing under this title~~safety assessment or safety determination under section 6~~.

Commented [B19]: Clarifies that R&D efforts extend to all testing under this title

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(d) Testing Requirements.—

"(1) IN GENERAL.—The Administrator may require the development of information by—

"(A) manufacturers and processors of the chemical substance or mixture; and

"(B) persons that begin to manufacture or process the chemical substance or mixture—

"(i) after the effective date of the ~~regulation~~rule, testing consent agreement, or order; but

"(ii) subject to paragraph (3), before the period ending on the date that is 180 days after the end of the period described in this section.

"(2) DESIGNATION.—The Administrator may permit 2 or more persons identified in subparagraph (A) or (B) of paragraph (1) to designate 1 of the persons or a qualified third party—

"(A) to develop the information; and

"(B) to submit the information on behalf of the persons making the designation.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—A person otherwise subject to a ~~regulation~~rule, testing consent agreement, or order under this section may submit to the Administrator an application for an exemption on the basis that the information is being developed by a person designated under paragraph (2).

"(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

"(i) IN GENERAL.—If the Administrator accepts an application submitted under subparagraph (A), the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as

agreed to between the applicant and the designee.

"(ii) ARBITRATION.—If the applicant and a person designated under paragraph (2) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.

"(C) TERMINATION.—If, after granting an exemption under this paragraph, the Administrator determines that a person covered by the exemption has failed to comply with the ~~regulation~~rule, testing consent agreement, or order, the Administrator shall—

"(i) by order, terminate the exemption; and

"(ii) notify in writing each person that received an exemption of the requirements with respect to which the exemption was granted.

"(e) Transparency.—Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders and all information submitted under this section.".

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the third sentence by striking "section 4(e)" and inserting "section 4(f)".

SEC. 6. PRIORITIZATION SCREENING.

The Toxic Substances Control Act is amended by inserting after section 4 (15 U.S.C. 2603) the following:

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) Establishment and List of Substances.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish, by ~~regulation~~rule, a risk-based screening process and **explicit** criteria for identifying existing chemical substances that are—

"(A) a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances'); and

"(B) a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').

"(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(A) IN GENERAL.—Before the date of promulgation of the ~~regulation~~ rule under paragraph (1) and not later than 180 days after the date of enactment of this section, the Administrator—

"(i) shall take into consideration and publish an initial list of high-priority substances **and low-priority substances**; and

"(ii) pursuant to section 6(b)~~(2)~~, may initiate or continue safety assessments and safety determinations for those ~~chemical~~ **high-priority** substances.

"(B) REQUIREMENTS.—

"(i) The initial list of ~~high-priority~~ chemical substances shall contain at least 10 ~~high priority substances~~, at least 5 of which are drawn from the list of chemical substances identified by the Administrator in the October, 2014 TSCA Work Plan and subsequent updates; ~~chemical high-priority substances and at least 10~~ **low-priority** substances; and

"(ii) insofar as possible, at least 50 percent of all substances subsequently identified by the Administrator as high-priority substances shall be drawn from the list of chemical substances identified by the Administrator in the October, 2014 TSCA Work Plan and subsequent updates, until all Work Plan chemicals have been designated under this subsection.

"(C) Additional Chemical Reviews.—The Administrator shall, as soon as practicable and no later than 5 years from the date of enactment of this Act, add additional high-priority substances sufficient to ensure that at least 20 high-priority substances have undergone or are undergoing safety assessments and determinations, and additional low-priority substances sufficient to ensure that at least 20 low-priority substances have been designated.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator shall take into consideration active substances, as determined under section 8, which may include chemical substances on the interim list of active substances established under that section.

"(ii) INACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator may take into consideration inactive substances, as determined under section 8, that the Administrator determines—

"(I)(aa) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) have the potential for high hazard and widespread exposure; or

"(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) with respect to which there exists the potential for residual high hazards or widespread exposures not otherwise addressed by the regulatory or other action.

"(iii) REPOPULATION.—

"(I) IN GENERAL.—On the completion of a safety determination under section 6 for a chemical substance, the Administrator shall remove the chemical substance from the list of high-priority substances established under this subsection.

"(II) ADDITIONS.—The Administrator shall add at least 1 chemical substance to the list of high-priority substances for each chemical substance removed from the list of high-priority substances established under this

Formatted: Indent: Before: 0.83", First line: 0.33"

Formatted: Font: Bold

Commented [B20]: Ensures that at least 50 percent of initial and subsequent chemicals are drawn from TSCA Work Plan (which identified chemicals on the basis of hazard, exposure, persistence and bioaccumulative characteristics) are addressed, until all Work Plan chemicals are designated.

Commented [B21]: Accelerates throughput in a time frame consistent with anticipated schedule for safety assessments on initial list, development of fee regulation and collection of fees.

Formatted: Indent: Before: 0.5", First line: 0.33"

subsection, until a safety assessment and safety determination is completed for all high-priority substances.

"(III) LOW-PRIORITY SUBSTANCES.—If a low-priority substance is subsequently designated as a high-priority substance, the Administrator shall remove that substance from the list of low-priority substances.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) not later than 180 days after the effective date of the final ~~regulation~~ rule under paragraph (1), begin the prioritization screening process; and

"(II) make every effort to complete the ~~prioritization screening~~ **designation** of all active **substances as high-priority substances or low-priority** substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a ~~regulation~~rule, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical substance as a high-priority substance or low-priority substance.

"(iii) CONSIDERATION.—

"(I) IN GENERAL.—The Administrator shall screen substances **and designate high-priority substances** taking into consideration the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in a timely manner.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.

"(C) SCREENING OF CATEGORIES OF SUBSTANCES.—The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate **designations of high-priority substances and low-priority substances and** safety assessments and safety determinations **for high-priority substances**.

"(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—Not less frequently than once each year, the Administrator shall publish a list of chemical substances that—

"(i) are being considered in the prioritization screening process and the status of the chemical substances in the prioritization process, including those chemical substances for which prioritization decisions have been deferred; and

"(ii) are designated as high-priority substances or low-priority substances, including the bases for such designations.

"(4) CRITERIA.—The criteria described in paragraph (1) shall account for—

"(A) the recommendation of the Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances

appropriate for prioritization screening;

"(B) the hazard and exposure potential of the chemical substance (or category of substances), including specific scientific classifications and designations by authoritative governmental entities;

"(C) the ~~intended or reasonably anticipated~~ conditions of use or significant changes in the conditions of use of the chemical substance;

"(D) evidence and indicators of exposure potential to humans or the environment from the chemical substance, including potentially exposed or susceptible populations;

"(E) the volume of a chemical substance manufactured or processed;

"(F) whether the volume of a chemical substance as reported under a ~~regulation~~ rule promulgated pursuant to section 8(a) has significantly increased or decreased during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance;

"(G) the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

"(H) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a low-priority substance.

"(b) Prioritization Screening Process and Decisions.—

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall include a requirement that the Administrator shall—

"(A) identify the chemical substances being considered for prioritization;

"(B) request interested persons to supply information regarding the chemical substances being considered;

"(C) apply the criteria identified in subsection (a)(4); and

"(D) subject to paragraph (5) and using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.

"(2) INTEGRATION OF INFORMATION.—The prioritization screening decision regarding a chemical substance shall integrate any hazard and exposure information relating to the chemical substance that is available to the Administrator.

"(3) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(A) shall identify as a high-priority substance a chemical substance that, relative to other chemical substances, the Administrator determines has the potential for high hazard and widespread exposure;

"(B) may identify as a high-priority substance a chemical substance that, relative to other chemical substances, the Administrator determines has the potential for high hazard or widespread exposure; and

"(C) may identify as a high-priority substance an inactive substance, as determined under subsection (a)(3)(A)(ii) and section 8(b), that the Administrator determines warrants a safety assessment and safety determination under section 6.

"(4) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that the chemical substance is likely to meet the applicable safety standard.

"(5) DEFERRING A DECISION.—If the Administrator determines that additional information is required to establish the priority of a chemical substance under this section, the Administrator may defer the prioritization screening decision for a reasonable period—

"(A) to allow for the submission of additional information by an interested person and for the Administrator to evaluate the additional information; or

"(B) to require the development of information pursuant to a ~~regulation~~rule, testing consent agreement, or order issued under section 4(a)(2).

"(6) DEADLINES FOR SUBMISSION OF INFORMATION.—If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of the information.

"(7) NOTICE AND COMMENT.—The Administrator shall—

"(A) publish the proposed decisions made under paragraphs (3), (4), and (5) and the basis for the decisions; and

"(B) provide an opportunity for public comment.

"(8) REVISIONS OF PRIOR DESIGNATIONS ~~BASED ON NEW INFORMATION~~.—

"(A) IN GENERAL.—At any time, and at the discretion of the Administrator, the Administrator may revise the designation of a chemical substance as a high-priority substance or a low-priority substance based on ~~new~~ information ~~made~~ available to the Administrator after the date of the determination under paragraph (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.

"(9) **OTHER INFORMATION RELEVANT TO PRIORITIZATION.—**

"(A) IN GENERAL.—If, after the date of enactment of the Chemical Safety Improvement Act, a State proposes an administrative action or **enacts a statute or takes an administrative action to ~~restrict or~~ prohibit** or otherwise restrict **the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not as designated a high-priority substance, the Governor or State agency with responsibility for implementing the statute or**

administrative action shall notify the Administrator.

"(B) REQUESTS FOR INFORMATION.—Following receipt of a notification provided under subparagraph (A), the Administrator may request any available information from the Governor or the State agency with respect to—

"(i) scientific evidence related to the hazards, exposures and risks of the chemical substance under the ~~intended~~ conditions of use which the statute or administrative action is intended to address;

"(ii) any State or local conditions which warranted the statute or administrative action;

"(iii) the statutory or administrative authority on which the action is based; and

"(iv) any other available information relevant to the prohibition or other restriction ~~or prohibition~~, including information on any alternatives considered and their hazards, exposures, and risks.

Commented [B22]: Reference to "prohibition or other restriction", or "prohibit or otherwise restrict" conformed throughout the bill for clarity

"(C) PRIORITIZATION SCREENING.—The Administrator shall conduct a prioritization screening under this subsection for all substances that—

"(i) are the subject of notifications received under subparagraph (A); and

"(ii) the Administrator determines—

"(I) are likely to have significant health or environmental impacts;

"(II) are likely to have significant impact on interstate commerce; or

"(III) have been subject to a ~~restriction or a~~ prohibition or other restriction under a statute or administrative action in 2 or more States.

"(D) AVAILABILITY TO PUBLIC.—Subject to section 14 and any applicable State law regarding the protection of confidential information provided to the State or to the Administrator, the Administrator shall make information received from a Governor or State agency under subparagraph (A) publicly available.

"(E) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall preempt a State statute or administrative action, require approval of a State statute or administrative action, or ~~subject a State to~~apply section 15 to a State.

"(10) REVIEW.—Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Administrator shall—

"(A) review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and

"(B) if necessary, modify the prioritization screening process.

~~"(10)~~**"(11)** EFFECT.—Subject to section 18, a designation by the Administrator under this section with respect to a chemical substance shall not affect—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance; or

"(B) the regulation of those activities.

~~"(c) Expedited Prioritization Screening.—~~ **Screening Requested by States.—**

Commented [B23]: Struck by request

~~"(1) IN GENERAL.—Not later than 180 days after the date on which the Administrator receives from the Governor of a State or a State agency with responsibility for protecting health and the environment a recommendation and relevant information justifying that an active a substance be identified~~ **designated under paragraph (3) or (4) of subsection (b)** ~~as a high-priority substance or a low-priority substance, the Administrator shall make a prioritization screening decision for the active substance.~~

~~"(2) LIMITATION.—The Governor of a State or a State agency with responsibility for protecting health and the environment may annually recommend not more than 2 chemical substances for prioritization screening under paragraph (1).~~

~~"(3) RECOMMENDATION.—Notwithstanding subsection (b)(8), a recommendation by the Governor of a State or a State agency with responsibility for protecting health and the environment with respect to a chemical substance that has been previously prioritized shall not be required to be based on new information.~~

~~"(4) NOTICE AND COMMENT.—The public shall be provided notice and an opportunity to comment regarding the recommendations submitted under this subsection.~~

~~"(5) EXPLANATION OF REASONS.—The Administrator shall—~~

~~"(A) make available to the Governor or State agency, as applicable, and to the public a brief explanation of the reasons for—~~

~~"(i) identifying a chemical substance recommended by the Governor or State agency for prioritization screening as a high-priority substance or a low-priority substance; or~~

~~"(ii) deferring a prioritization screening decision; and~~

~~"(B) identify the information relied on in making that identification.~~

"(~~c~~d) ~~Treatment.—Except as provided in section 18(e)(6)(B), an~~ **Additional Priorities for Safety Assessments and Determinations.—**

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall—

"(A) include a process by which a manufacturer or processor of an active chemical substance that has not been designated a high-priority substance, or that has not been subject to or is not in the process of a prioritization screening by the Administrator, may request that the Administrator designate the substance for a safety assessment and safety determination, subject to the payment of fees pursuant to section 26(b)(3)(E); and

"(B) provide guidance to submitters on the information to be provided in such requests, and specify the criteria the Administrator shall use to determine whether or not to grant such a request, which shall include whether the substance is subject to restrictions imposed by statutes enacted or administrative actions taken by 1 or more States on the manufacture, processing, distribution in

commerce, or use of the substance.

"(2) PREFERENCE.—Subject to paragraph (3), in deciding whether to grant requests under this subsection the Administrator shall give a preference to requests concerning substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

"(3) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

"(A) not more than 15 percent of the total number of substances designated to undergo safety assessments and safety determinations under this section are substances designated under the process and criteria pursuant to paragraph (1); and

"(B) the resources allocated to conducting safety assessments and safety determinations for additional priorities designated under this subsection are proportionate to the number of such substances relative to the total number of substances designated to undergo safety assessments and safety determinations under this section.

"(4) REQUIREMENTS.—

"(A) IN GENERAL.—The public shall be provided notice and an opportunity to comment on requests submitted under this subsection.

"(B) DECISION BY ADMINISTRATOR.—Not later than 180 days after the date on which the Administrator receives a request under this subsection, the Administrator shall decide whether or not to grant the request.

"(C) ASSESSMENT AND DETERMINATION.—If the Administrator grants a request under this subsection, the safety assessment and safety determination—

"(i) shall be conducted in accordance with the deadlines and other requirements of sections 3A(i~~k~~) and 6; and

"(ii) shall not be expedited or otherwise subject to special treatment relative to high-priority substances designated pursuant to subsection (b)(3) that are undergoing safety assessments and safety determinations.

"(5) EXCEPTIONS.—Requests granted under this subsection shall not be subject to subsection (a)(3)(A)(iii) or section 18(b).".

~~"(e) Treatment.—An action by the Administrator under this section shall not be—~~

~~"(1) considered to be a final agency action; or~~

~~"(2) subject to judicial review.".~~

SEC. 7. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.";

(2) by striking subsection (b);

(3) by redesignating subsection (a) as subsection (b);

(4) by redesignating subsection (i) as subsection (a) and moving the subsection so as to appear at the beginning of the section;

(5) in subsection (b) (as so redesignated)—

(A) in the subsection heading, by striking "In General" and inserting "Notices"; and

(B) in paragraph (1), in the matter following subparagraph (B)—

(i) by striking "subsection (d)" and inserting "subsection (b)"; and

(ii) by striking "and such person complies with any applicable requirement of subsection (b)";

(6) by redesignating subsections (c) and (d) as subsection (d) and (c), respectively, and moving subsection (c) (as so redesigned) so as appear after subsection (b) (as redesignated by paragraph (3));

(7) in subsection (c) (as so redesignated)—

(A) by striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—The notice required by subsection (a) shall include, with respect to a chemical substance—

"(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

"(B) information regarding ~~intended or reasonably anticipated~~ conditions of use and reasonably anticipated exposures.";

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking "or of data under subsection (b)";

(ii) in subparagraph (A), by adding "and" after the semicolon at the end;

(iii) in subparagraph (B), by striking "; and" and inserting a period; and

(iv) by striking subparagraph (C); and

(C) in paragraph (3), by striking "subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "subsection (b) and for which the notification period prescribed by subsection (b) or (d)";

(8) by striking subsection (d) (as redesignated by paragraph (6)) and inserting the following:

"(d) Review of Notice.—

"(1) INITIAL REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall—

"(i) conduct an initial review of the notice;

"(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

"(iii) make any necessary determination under paragraph (3).

"(B) EXTENSION.—Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.

"(2) INFORMATION SOURCES.—In evaluating a notice under paragraph (1), the Administrator shall take into consideration—

"(A) any relevant information identified in subsection (c)(1); and

"(B) any other relevant additional information available to the Administrator.

"(3) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), and based on the information described in paragraph (2), the Administrator shall determine that—

"(A) the relevant chemical substance or significant new use is not likely to meet the safety standard, in which case the Administrator shall take appropriate action under paragraph (45);

"(B) the relevant chemical substance or significant new use is likely to meet the safety standard, in which case the Administrator shall allow the review period to expire without additional restrictions; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (5).

"(4) RESTRICTIONS.—

"(A) IN GENERAL.—

"(i) If the Administrator makes a determination under subparagraph (A) or (C) of paragraph (3) with respect to a notice submitted under subsection (b)—

Formatted: Indent: Before: 0.83"

"(I), the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, as appropriate, shall prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the restrictions specified in the consent agreement or order that the Administrator determines are sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard; and

Formatted: Indent: Before: 1"

"(II) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, except in compliance with the restrictions specified in the consent agreement or order.

"(ii) If the Administrator makes a determination under subparagraph (B) of paragraph (3) with respect to a chemical substance or significant new use for which a notice was submitted under subsection (b), at the end of the applicable period for review under paragraph (1), the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use.

"(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall—

"(i) take into consideration whether to promulgate a ~~regulation~~ rule pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance, or of the chemical substance for a new use, that is not in compliance with the restrictions imposed by the consent agreement or order; and

"(ii)(I) initiate a rulemaking described in clause (i); or

"(II) publish a statement describing the reasons of the Administrator for not initiating a rulemaking.

"(C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include, as appropriate—

"(i) a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the warnings and instructions to be prescribed by the Administrator;

"(ii) a requirement that manufacturers ~~and~~or processors of the chemical substance shall—

"(I) make and retain records of the processes used to manufacture or process, as applicable, the chemical substance; or

"(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, use, or disposal, as applicable, of the chemical substance, subject to section 4;

"(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

"(I) in general; or

"(II) for a particular use;

"(iv) a prohibition or other ~~regulation~~ restriction of—

Commented [B24]: Clarifies circumstances under which a new chemical or significant new use subject to consent agreement or order may be commenced.

Formatted: Indent: Before: 0.83"

Commented [B25]: Clarifies that substances likely to meet the safety standard can proceed to manufacture.

"(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

"(II) any method of commercial use of the chemical substance; or

"(III) any method of disposal of the chemical substance; or

"(v) a prohibition or other ~~appropriate~~ restriction on the manufacture, processing, or distribution in commerce of the chemical substance—

"(I) in general; or

"(II) for a particular use.

"(D) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

"(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(C) may promulgate a ~~regulation~~rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

"(D) on receipt of information the Administrator finds supports the determination under paragraph (3), shall promptly make the determination.

"(6) REGULATION PENDING DEVELOPMENT OF INFORMATION.—Subject to paragraph (4)(B), the Administrator may permit manufacture for commercial purposes of a chemical substance to commence pending receipt of the additional information, subject to compliance with any restrictions under paragraph (4) determined by the Administrator to be sufficient to ensure that the chemical substance is likely to meet the safety standard.

"(7) COMMENCEMENT OF MANUFACTURE.—Subject to paragraphs (4), (5), and (6), at the end of the applicable period for review under paragraph (1), the submitter of a notice under subsection (a) may commence manufacture for commercial purposes of a chemical substance or a chemical substance for a significant new use.";

(9) by striking subsections (e) through (g) and inserting the following:

"(e) Notice of Commencement.—

"(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer ~~or processor~~ that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer ~~or processor~~ shall submit to the Administrator a notice of commencement that identifies—

Commented [B26]: Notices of commencement cannot be made by a processor. Conforms to existing law.

"(A) the name of the manufacturer ~~or processor~~, and

"(B) the initial date of nonexempt commercial manufacture.

"(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

"(f) Further Evaluation.—The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—

"(1) a notice of commencement for a chemical substance under subsection (c); or

"(2) new information regarding the chemical substance.

"(g) Transparency.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, consent agreements, ~~regulations~~rules, and orders of the Administrator; and

"(2) all information submitted or issued under this section.";

(10) in subsection (h)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking "(a) or";

(B) by striking paragraph (2);

(C) by redesignating paragraphs (3) through (6) as paragraphs (2) through (5), respectively;

(D) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking "subsections (a) and (b)" and inserting "subsection (b)";

(E) in paragraph (3) (as so redesignated)—

(i) in the first sentence, by striking "will not present an unreasonable risk of injury to health or the environment" and inserting "will meet the safety standard"; and

(ii) by striking the second sentence;

(F) in paragraph (4) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (b)"; and

(G) in paragraph (5) (as so redesignated), in the first sentence, by striking "paragraph (1) or (5)" and inserting "paragraph (1) or (4)~~,~~.";~~ and~~

~~(11) by adding at the end the following:~~

~~"(i) Prior Actions.—Nothing in this section requires the Administrator to modify or withdraw any regulation or order promulgated pursuant to this section before the date of enactment of the Chemical Safety Improvement Act.".~~

Formatted: Indent: Before: 0.67"

Commented [B27]: Moved to Section 26(h)

SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections (g~~h~~) and (h~~i~~), respectively;

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) shall, as soon as practicable and not later than 6 months after the date on which a chemical substance is designated as a high-priority substance, define the scope of the safety assessment and determination to be conducted pursuant to this section, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that the Administrator expects to consider;

"(3) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(4~~3~~) shall complete a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

"(5~~4~~) shall promulgate a final ~~regulation~~ rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; and

"(6~~5~~) may extend any deadline under this subsection for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under paragraphs (4~~3~~) and (5~~4~~) and any deferral under subsection (c)(2) does not exceed 2 years.

"(b) Prior Actions.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination that was initiated before the date of enactment of the Chemical Safety Improvement Act, prior to the effective date of the policies and procedures required to be established by the Administrator under section 3A or 4A.

"(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or ~~regulation~~ rule solely because the action was completed prior to the completion of a policy or procedure established under

Commented [B28]: Establishes a date by which the scope of the safety assessment and determination must be defined. Conforming change made in section 18.

section 3A or 4A, and the validity of a completed assessment, determination, or ~~regulation~~ rule shall not be determined based on the content of such a policy or procedure.

"(c) Safety Determinations.—

"(1) IN GENERAL.—Based on a review of the information available to the Administrator, including draft safety assessments submitted by interested persons, the Administrator shall determine that—

"(A) the relevant chemical substance meets the safety standard;

"(B) the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by ~~regulation~~ rule under subsection (d)—

"(i) impose restrictions necessary to ensure that the chemical substance meets the safety standard under the intended or reasonably anticipated conditions of use; or

"(ii) if the safety standard cannot be met with the application of restrictions, ban or phase out the chemical substance, as appropriate; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is necessary to make a safety assessment or safety determination for a high-priority substance, the Administrator—

"(A) shall provide an opportunity for interested persons to submit the additional information;

"(B) may promulgate a ~~regulation~~rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

"(C) may defer, for a reasonable period consistent with the deadlines described in subsection (a), a safety assessment and safety determination until after receipt of the information; and

"(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety determination, shall make a determination under paragraph (1).

"(3) ESTABLISHMENT OF DEADLINE.—In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.

"(d) ~~Regulation~~Rule.—

"(1) IMPLEMENTATION.—If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a ~~regulation~~ rule establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

"(2) SCOPE.—The ~~regulation~~ rule promulgated pursuant to this subsection—

"(A) may—

"(i) apply to mixtures containing the chemical substance, as appropriate; and

"(ii) exempt replacement parts for articles manufactured prior to the applicable compliance deadline; and

"(B) shall include dates by which compliance is mandatory, which—

"(i) shall be as soon as practicable; and

"(ii) as determined by the Administrator, may vary for different affected persons.

"(C) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(3) RESTRICTIONS.—A restriction under paragraph (1) may include, as appropriate—

"(A) subject to section 18, a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the warnings and instructions to be prescribed by the Administrator;

"(B) a requirement that manufacturers ~~and~~ or processors of the chemical substance shall—

"(i) make and retain records of the processes used to manufacture or process the chemical substance;

"(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or

"(iii) monitor or conduct tests that are reasonably necessary to ensure compliance with the requirements of any ~~regulation~~ rule under this subsection;

"(C) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

"(D) a requirement to ban or phase out, or any other ~~regulation~~ rule regarding, the manufacture, processing, or distribution in commerce of the chemical substance for—

"(i) a particular use;

"(ii) a particular use at a concentration in excess of a level specified by the Administrator; or

"(iii) all uses;

"(E) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—

"(i) a particular use; or

"(ii) a particular use at a concentration in excess of a level specified by the Administrator;

"(F) a requirement to ~~restrict,~~ ban, ~~or~~ phase out, or ~~any~~ otherwise restrict ~~regulation of,~~ any method of commercial use of the chemical substance;

"(G) a requirement to ~~restrict,~~ ban, ~~or~~ phase out, or ~~any~~ otherwise restrict ~~regulation of,~~ any method of disposal of the chemical substance or any article containing the chemical substance; and

"(H) a requirement directing manufacturers or processors of the chemical substance to give notice of ~~unreasonable risks of harm~~ the Administrator's determination under subsection (c)(1)(B) to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

Commented [B29]: Separate references to "unreasonable risk" have been eliminated under this bill; conforming change.

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a ~~regulation~~ rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a ~~regulation~~ rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a ~~regulation~~ rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

"(5) EXEMPTIONS.—

"(A) IN GENERAL.—The Administrator may exempt 1 or more uses of a chemical substance from any restriction in a ~~regulation~~ rule promulgated under paragraph (1) if the Administrator determines that—

"(i) the ~~regulation~~ rule cannot be complied with, without—

"(I) harming national security;

"(II) causing significant disruption in the national economy due to the lack of availability of a chemical substance; or

"(III) interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or

"(ii) the use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to ~~human~~ health, the environment, or public safety.

"(B) EXEMPTION ANALYSIS.—In proposing a ~~regulation~~ rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall make publicly available any analysis conducted under this paragraph to assess the need for the exemption.

"(C) STATEMENT REQUIRED.—In making final a ~~regulation~~ rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall include a statement describing how the analysis considered under subparagraph (B) was taken into account.

"(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—In determining whether an exemption should be granted under this paragraph for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more technically and economically feasible alternatives to the chemical substance most likely to be used in place of the chemical substance under the ~~intended or reasonably anticipated~~ conditions of use if the ~~regulation~~ rule is promulgated.

"(E) CONDITIONS.—As part of a ~~regulation~~ rule promulgated under paragraph (1), the Administrator shall include conditions in any exemption established under this paragraph, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect ~~human~~ health and the environment while achieving the purposes of the exemption.

"(F) DURATION.—

"(i) IN GENERAL.—The Administrator shall establish, as part of a ~~regulation~~ rule under paragraph (1) that contains an exemption under this paragraph, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis.

"(ii) AUTHORITY OF ADMINISTRATOR.—The Administrator, by ~~regulation~~rule, may extend, modify, or eliminate the exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or is no longer necessary.

"(iii) CONSIDERATIONS.—

"(I) IN GENERAL.—Subject to subclause (II), the Administrator shall issue exemptions and establish time periods by considering factors determined by the Administrator to be relevant to the goals of fostering innovation and the development of alternatives that meet the safety standard.

"(II) LIMITATION.—Any renewal of an exemption in the case of a ~~regulation~~ rule requiring the ban or phase-out of a chemical substance shall not exceed 5 years.

"(e) Immediate Effect.—The Administrator may declare a proposed ~~regulation~~ rule under subsection (d) to be effective on publication of the ~~regulation~~ rule in the Federal Register and until the effective date of final action taken respecting the ~~regulation~~rule, if—

"(1) the Administrator determines that—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to the proposed ~~regulation~~ rule or any combination of those activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before the effective date; and

"(B) making the proposed ~~regulation~~ rule so effective is necessary to protect the public interest; and

"(2) in the case of a proposed ~~regulation~~ rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under paragraph (1)(A), a court has granted relief in an action under section 7 with respect to that risk associated with the chemical substance or mixture.

"(f) Final Agency Action.—Under this section—

"(1) a safety determination, and the associated safety assessment, for a chemical substance that the Administrator determines under subsection (c) meets the safety standard, shall be considered to be a final agency action, effective beginning on the date of issuance of the final safety determination; and

"(2) a final ~~regulation~~ rule promulgated under subsection (d), and the associated safety assessment and safety determination that a chemical substance does not meet the safety standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final ~~regulation~~rule.";

(4) in subsection (~~g~~h) (as redesignated by paragraph (2))—

(A) by striking paragraph (4); and

(B) by redesignating paragraph (5) as paragraph (4)~~; and~~

~~(5) by adding at the end the following:~~

~~"(j) Prior Actions.—Nothing in this section requires the Administrator to modify or withdraw any regulation or order promulgated pursuant to this section, as in effect on the day before the date of enactment of the Chemical Safety Improvement Act.~~".

Formatted: Indent: Before: 0.67"

Commented [B30]: Moved to section 26(h)

SEC. 9. IMMINENT HAZARDS.

Section 7 of the Toxic Substances Control Act (15 U.S.C. 2606) is amended—

(1) by striking subsection (a) and inserting the following:

"(a) Civil Actions.—

"(1) IN GENERAL.—The Administrator may commence a civil action in an appropriate United States district court for—

"(A) seizure of an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture;

"(B) relief (as authorized by subsection (b)) against any person that manufactures, processes, distributes in commerce, uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing the chemical substance or

mixture; or

"(C) both seizure described in subparagraph (A) and relief described in subparagraph (B).

"(2) ~~REGULATION~~RULE, ORDER, OR OTHER PROCEEDING.—A civil action may be commenced under this paragraph, notwithstanding—

"(A) the existence of—

"(i) a decision by the Administrator under section 4A, 5(d)(3), or 6(c)(1); or

"(ii) a ~~regulation~~rule, testing consent agreement, or order under section 4, 5(d)(4), 6(d), or 6(h); or

"(B) the pendency of any administrative or judicial proceeding under any provision of this Act.";

(2) in subsection (d), by striking "section 6(a)" and inserting "section 6(c)"; and

(3) in subsection (f), in the first sentence, by striking "and unreasonable".

SEC. 10. INFORMATION COLLECTION AND REPORTING.

Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amended—

(1) in subsection (a)—

(A) in paragraph (3)(A)(ii)(I)—

(i) by striking "5(b)(4)" and inserting "5";

(ii) by inserting "section 4 or" after "in effect under"; and

(iii) by striking "5(e)," and inserting "5(d)(4);"; and

(B) by adding at the end the following:

"(4) ~~REGULATIONS~~RULES.—

"(A) DEADLINE.—

"(i) IN GENERAL.—Not later than 2 years after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall promulgate ~~regulations~~ rules requiring the maintenance of records and the reporting of information known or reasonably ascertainable by the person making the report, including ~~regulations~~ rules requiring processors to report information, so that the Administrator has the information necessary to carry out sections 4 and 6.

"(ii) MODIFICATION OF PRIOR ~~REGULATIONS~~RULES.—In carrying out this subparagraph, the Administrator may modify, as appropriate, ~~regulations~~ rules promulgated before the date of enactment of the Chemical Safety Improvement Act.

"(B) CONTENTS.—The ~~regulations~~ rules promulgated pursuant to subparagraph (A)—

"(i) may impose different reporting and recordkeeping requirements on

Commented [B31]: Clarify that requirements include recordkeeping

manufacturers and processors; and

"(ii) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported; and

~~"(iii) shall apply only in cases in which the Administrator determines that the submission of reports would assist in the effective implementation of this Act.~~

"(C) ADMINISTRATION.—In implementing the reporting and recordkeeping requirements under this paragraph, the Administrator shall take measures—

"(i) to limit the potential for duplication in reporting requirements;

"(ii) to minimize the impact of the ~~regulations~~ rules on small manufacturers and processors; and

"(iii) to apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.

"(5) GUIDANCE.—The Administrator shall develop guidance relating to the information required to be reported under the ~~regulations~~ rules promulgated under this subsection.";

(2) in subsection (b), by adding at the end the following:

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Chemical Safety Improvement Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

"(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

"(I) cement, Portland, chemicals, CAS No. 65997–15–1;

"(II) cement, alumina, chemicals, CAS No. 65997–16–2;

"(III) glass, oxide, chemicals, CAS No. 65997–17–3;

"(IV) frits, chemicals, CAS No. 65997–18–4;

"(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

"(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature

conventions, the Administrator shall—

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

"(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) ~~REGULATIONS~~RULES.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, the Administrator, by ~~regulation~~rule, shall require manufacturers and processors to notify the Administrator, by not later than 180 days after the date of promulgation of the ~~regulation~~rule, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Chemical Safety Improvement Act.

"(ii) ACTIVE SUBSTANCES.—The Administrator shall, pursuant to paragraph (5)(A), designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—The ~~regulation~~ rule promulgated by the Administrator pursuant to subparagraph (A) shall require—

"(i) the Administrator to maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

"(ii) a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

"(iii) the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C).

"(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a ~~regulation~~ rule that establishes a plan to review all

claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are notified pursuant to subparagraph (A) or identified as active substances under subsection (f)(1).

"(D) REQUIREMENTS OF REVIEW PLAN.—The review plan under subparagraph (C) shall—

"(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

"(ii) require the Administrator, in accordance with section 14—

"(I) to review each substantiation—

"(aa) submitted pursuant to clause (i) to determine if the claim warrants protection from disclosure; and

"(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

"(II) approve, modify, or deny each claim; and

"(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(iii) encourage manufacturers or processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

"(E) TIMELINE FOR COMPLETION OF REVIEWS.—

"(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

"(ii) CONSIDERATIONS.—

"(I) IN GENERAL.—The Administrator may extend the deadline for

completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of applicable claims needing review and the available resources.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of reviews to be completed over the course of implementation of the plan.

~~"(F) LIMITATION.—The specific identity of any chemical substance that is not on the confidential portion of the list published under paragraph (1) or subsequently added to the confidential portion of the list pursuant to section 14 shall not be eligible for protection from disclosure.~~

~~"(G) CERTIFICATION.—The regulation under this subsection shall require a manufacturer or processor—~~

~~"(i) to certify the accuracy of each report of the manufacturer or processor carried out under the regulation; and~~

~~"(ii) to retain a record supporting that certification for a period of 5 years beginning on the last day of the submission period.~~

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

"(A) IN GENERAL.—The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).

"(B) UPDATE.—The Administrator shall update the list of chemical substances designated as active substances as soon as practicable after the date of publication of the most recent data reported under—

"(i) part 711 of title 40, Code of Federal Regulations (or successor regulations); and

"(ii) the regulations promulgated pursuant to subsection (a)(4).

"(C) CHANGE TO ACTIVE STATUS.—

"(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

"(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—

~~"(I) IN GENERAL.—~~If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the inactive substance as confidential, the person shall—

"(I~~aa~~) in the notice submitted under clause (i), assert the claim; and

"(II~~bb~~) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

Commented [B32]: Moved, modified and consolidated under new paragraphs (8) and (9) below.

Formatted: Indent: Before: 1"

~~"(II) LIMITATION.—The specific identity of any inactive substance that is not on the confidential portion of the list published under paragraph (1) or subsequently added to the confidential portion of the list pursuant to section 14 shall not be eligible for protection from disclosure.~~

Commented [B33]: Moved, modified and consolidated in paragraphs (8) and (9) below.

"(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

"(I) designate the applicable chemical substance as an active substance;

"(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific identity of the chemical substance and approve, modify, or deny the claim;

"(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of not less than 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines to be necessary.

"(D) CATEGORY STATUS.—The list of inactive substances shall not be considered to be a category for purposes of section 26(c).

"(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the ~~regulation~~ rule required under this subsection, the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (or successor regulations), during the reporting period that most closely preceded the date of enactment of the Chemical Safety Improvement Act, as the ~~initial~~interim list of active substances for the purposes of section 4A.

"(7) PUBLIC PARTICIPATION.—Subject to this subsection, the Administrator shall make available to the public—

"(A) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—

"(i) an active substance; or

"(ii) an inactive substance;

"(B) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list

published under paragraph (1) for which a claim of confidentiality was received and approved by the Administrator pursuant to section 14; and

"(C) subject to section 14(g), the specific identity of any active substance for which—

"(i) no claim of protection against disclosure of the specific identity of the active substance pursuant to this subsection was received;

"(ii) a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or

"(iii) the time period for protection against disclosure of the specific identity of the active substance has expired.";

"(8) LIMITATION.—No person may assert a new claim under this subsection for protection from disclosure of a specific identity of any active or inactive chemical substance for which a notice is received under paragraph (4)(A)(i) or paragraph (5)(B)(i) that is not on the confidential portion of the list published under paragraph (1).

Commented [B34]: Clarifies the application of these provisions to the entire subsection.

Formatted: Indent: Before: 0.33"

"(9) CERTIFICATION.—Under the rule promulgated under this subsection, manufacturers and processors shall be required—

"(A) to certify that each report the manufacturer or processor submits complies with the requirements of the rule, and that any confidentiality claims are true and correct; and

Formatted: Indent: Before: 0.5"

"(B) to retain a record supporting the certification for a period of 5 years beginning on the last day of the submission period.";

(3) in subsection (e)—

(A) by striking "Any person" and inserting the following:

"(1) IN GENERAL.—Any person"; and

(B) by adding at the end the following:

"(2) APPLICABILITY.—Any person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of injury to ~~human~~ health and the environment."; and

(4) in subsection (f), by striking "For purposes of this section, the" and inserting the following: "In this section:

"(1) ACTIVE SUBSTANCE.—The term 'active substance' means a chemical substance—

"(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Chemical Safety Improvement Act;

"(B) that is added to the list published under subsection (b)(1) after that date of enactment; or

"(C) for which a notice is received under subsection (b)(5)(C).

"(2) INACTIVE SUBSTANCE.—The term 'inactive substance' means a chemical substance

on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).

"(3) MANUFACTURE; PROCESS.—The".

SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.

Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the first sentence—

(i) by striking "presents or will present an unreasonable risk to health or the environment" and inserting "does not meet the safety standard"; and

(ii) by striking "such risk" the first place it appears and inserting "the risk posed by the substance or mixture";

(B) in paragraph (2), in the matter following subparagraph (B), by striking "section 6 or 7" and inserting "section 6(d) or section 7"; and

(C) in paragraph (3), by striking "section 6 or 7" and inserting "section 6(d) or 7"; and

(2) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

SEC. 12. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA.

Section 10 of the Toxic Substances Control Act (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".

SEC. 13. EXPORTS.

Section 12 of the Toxic Substances Control Act (15 U.S.C. 2611) is amended—

(1) in subsection (a), by striking paragraph (2) and inserting the following:

"(2) EXCEPTION.—Paragraph (1) shall not apply to any chemical substance that the Administrator determines—

"(A) under section 5 is not likely to meet the safety standard; or

"(B) under section 6 does not meet the safety standard.

"(3) WAIVERS.—For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—

"(A) determine that paragraph (1) shall not apply to the mixture or article; or

"(B) establish a threshold concentration in a mixture or article at which paragraph (1) shall not apply.

"(4) TESTING.—The Administrator may require testing under section 4 of any chemical

substance or mixture exempted from this Act under paragraph (1) for the purpose of determining whether the chemical substance or mixture ~~presents an unreasonable risk of harm to human health~~meets the safety standard within the United States ~~or to the environment of the United States~~.";

Commented [B35]: Conforming change.

(2) by striking subsection (b) and inserting the following:

"(b) Notice.—

"(1) IN GENERAL.—A person shall notify the Administrator that the person is exporting or intends to export to a foreign country—

"(A) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 5 is not likely to meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(B) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 6 does not meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(C) a chemical substance for which the United States is obligated by treaty to provide export notification;

"(D) a chemical substance or mixture subject to a prohibition or other restriction pursuant to a ~~regulation~~rule, order, or consent agreement in effect under this Act; or

"(E) a chemical substance or mixture for which the submission of information is required under section 4.

"(2) ~~REGULATIONS~~RULES.—

"(A) IN GENERAL.—The Administrator shall promulgate ~~regulations~~ rules to carry out paragraph (1).

"(B) CONTENTS.—The ~~regulations~~ rules promulgated pursuant to subparagraph (A) shall—

"(i) include such exemptions as the Administrator determines to be appropriate, which may include exemptions identified under section 5(h); and

"(ii) indicate whether, or to what extent, the ~~regulations~~ rules apply to articles containing a chemical substance or mixture described in paragraph (1).

"(3) NOTIFICATION.—The Administrator shall submit to the government of each country to which a chemical substance or mixture is exported—

"(A) for a chemical substance or mixture described in subparagraph (A), (B), or (D) of paragraph (1), a notice of the determination, ~~regulation~~rule, order, consent agreement, requirement, or designation;

"(B) for a chemical substance described in paragraph (1)(C), a notice that satisfies the obligation of the United States under the applicable treaty; and

"(C) for a chemical substance or mixture described in paragraph (1)(E), a notice of

availability of the information on the chemical substance or mixture submitted to the Administrator."; and

(3) in subsection (c)—

(A) by striking paragraph (3); and

(B) by redesignating paragraphs (4) through (6) as paragraphs (3) through (5), respectively.

SEC. 14. IMPORTS.

Section 13 of the Toxic Substances Control Act (15 U.S.C. 2612) is amended to read as follows:

"SEC. 13. IMPORTS.

"(a) Refusal of Entry.—

"(1) IN GENERAL.—The Secretary of Homeland Security shall refuse entry into the customs territory of the United States (as defined in general note 2 to the Harmonized Tariff Schedule of the United States) any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry, if—

"(A) the Administrator—

"(i) has determined under section 6(c) that the chemical substance or mixture does not meet the safety standard; and

"(ii) has promulgated a ~~regulation~~ rule pursuant to section 6(d) banning the chemical substance or mixture, as of the effective date of the ~~regulation~~rule;

"(B) the chemical substance—

"(i) is not included on the list under section 8(b)(1); and

"(ii) is not exempt from any requirement to be included on that list by this title or a ~~regulation~~ rule promulgated by the Administrator pursuant to this title; or

"(C) the chemical substance, mixture, or any article containing the chemical substance or mixture is offered for entry in violation of—

"(i) a ~~regulation~~rule, consent agreement, or order in effect under this Act; or

"(ii) an order issued in a civil action brought under section 7 or title IV.

"(2) PROCEDURE.—

"(A) IN GENERAL.—Subject to subparagraph (B), if a chemical substance, mixture, or article containing a chemical substance or mixture is refused entry under paragraph (1), the Secretary of Homeland Security—

"(i) shall notify the consignee of the entry of the refusal;

"(ii) shall not release the chemical substance or mixture to the consignee; and

"(iii) shall cause the disposal or storage of the chemical substance or mixture under such ~~regulations~~ rules as the Secretary may prescribe, if the chemical

substance or mixture has not been exported by the consignee during the 90-day period beginning on the date of receipt of the notice of the refused entry.

"(B) EXCEPTION.—

"(i) IN GENERAL.—The Secretary of Homeland Security, pending a review by the Administrator, may release to the consignee the chemical substance or mixture if the consignee—

"(I) executes a bond for the amount of the full invoice of the chemical substance or mixture (as set forth in the customs entry); and

"(II) pays a duty on the chemical substance or mixture.

"(ii) ADMINISTRATION.—If a consignee fails to return a chemical substance or mixture released to that consignee under clause (i) for any cause to the custody of the Secretary of Homeland Security on demand, the consignee shall be liable to the United States for liquidated damages equal to the full amount of the bond executed under clause (i)(I).

"(C) STORAGE.—All charges for storage, cartage, and labor on or for the disposal of a chemical substance or mixture that is refused entry or released under this subsection shall be paid by the owner or consignee, and a default on that payment shall constitute a lien against any future entry made by the owner or consignee.

"(b) Certification.—

"(1) IN GENERAL.—A person offering a chemical substance or mixture subject to this Act for entry into the customs territory of the United States shall certify to the Secretary of Homeland Security that—

"(A) after reasonable inquiry and to the best knowledge and belief of the person, the chemical substance or mixture is in compliance with any applicable ~~regulation~~rule, consent agreement, or order under section 5 or 6; and

"(B) the chemical substance—

"(i) is included on the list under section 8(b)(1); or

"(ii) is exempt from any requirement to be included on that list by this title or a ~~regulation~~ rule promulgated by the Administrator pursuant to this title.

"(2) ARTICLES.—

"(A) IN GENERAL.—The Administrator, by ~~regulation~~rule, may require certification under paragraph (1) for an article containing a chemical substance or mixture that is subject to ~~regulation~~ rule under section 5 or 6.

"(B) REQUIREMENT.—The ~~regulation~~ rule under subparagraph (A) shall identify, with reasonable specificity, the types of articles, including parts or components of articles, that will be subject to the certification requirement.

"(C) FACTORS FOR CONSIDERATION.—In determining the need for and content of a certification ~~regulation~~ rule under this paragraph, the Administrator shall take into consideration—

"(i) the utility of the certification to enforcement of the applicable ~~regulation~~rule, consent agreement, or order under section 5 or 6;

"(ii) the contribution of imported articles to the potential risk presented by exposure to the chemical substance or mixture subject to ~~regulation~~ rule under section 5 or 6;

"(iii) the impact on commerce and potential for the certification to impede or disrupt import of articles;

"(iv) the frequency or duration of the certification requirement; and

"(v) specification of the concentration of a chemical substance in an article that would subject the article to the certification requirement.

"(3) REASONABLE INQUIRY.—

"(A) IN GENERAL.—For purposes of a certification under paragraph (1), reasonable inquiry shall include good faith reliance by an importer on—

"(i) a safety data sheet or similar declaration provided by a supplier that documents the specific identity of the chemical substance or the specific identities of all chemical substances in a mixture; or

"(ii) for chemical substances or mixtures claimed by the supplier as confidential, or not otherwise disclosed by the supplier, a certification by the supplier that the imported chemical substance or mixture satisfies the applicable certification requirements under paragraph (1).

"(B) ARTICLES.—For purposes of a certification under paragraph (2), reasonable inquiry shall include good faith reliance by an importer on a certification by the supplier that the imported article satisfies the applicable certification requirements in a ~~regulation~~ rule promulgated pursuant to paragraph (2).

"(4) INFORMATION REGARDING IDENTITY.—For purposes of this subsection, the Administrator shall provide publicly accessible information regarding the identity of a chemical substance or mixture subject to ~~regulation~~ rule under this Act that would be readily understood in import transactions.

"(c) Notice.—A person offering a chemical substance for entry into the customs territory of the United States shall notify the Secretary of Homeland Security if—

"(1) the chemical substance or chemical substance in a mixture is a high-priority substance;

"(2) the chemical substance or chemical substance in a mixture is 1 for which the United States is obligated to provide export notification by treaty; or

"(3) the chemical substance or chemical substance in a mixture—

"(A) is the subject of a safety assessment and safety determination conducted pursuant to section 6; and

"(B) has been found not to meet the safety standard.

"(d) ~~Regulations~~Rules.—

"(1) IN GENERAL.—The Secretary of Homeland Security, after consultation with the Administrator, shall promulgate ~~regulations~~ rules to carry out this section.

"(2) APPLICATION.—The ~~regulations~~ rules under paragraph (1) may modify the application of any requirement of this section, as appropriate for the efficient and effective implementation of this Act.".

SEC. 15. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

Commented [B36]: Ensures subsection (b) information must also meet FOIA exceptions.

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer and specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

"(7) Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if—

"(A) the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5; and

"(B) the claim—

"(i) is not subject to an exception under subsection (e); or

Commented [B37]: Clarifying change

Formatted: Indent: First line: 0.33"

"(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection ~~(e)~~, (f)(2), or (g).

"(c) Information Not Protected From Disclosure.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

"(1) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

"(A) IN GENERAL.—Subject to subparagraph (B), subsection (a) does not prohibit the disclosure of—

"(i) any health and safety study that is submitted under this Act with respect to—

"(I) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

"(II) any chemical substance or mixture for which—

"(aa) testing is required under section 4; or

"(bb) a notification is required under section 5; or

"(ii) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in subclause (I) or (II) of clause (i).

"(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph authorizes the release of any information that discloses—

"(i) a process used in the manufacturing or processing of a chemical substance or mixture; or

"(ii) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

"(2) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(3) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

"(A) For information submitted after the date of enactment of the Chemical Safety Improvement Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

"(B) A safety assessment developed, or a safety determination made, under section 6.

"(C) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in

ranges.

"(D) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

"(4) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is otherwise eligible for protection under this section and contained in a submission of information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

~~"(5) LIMITATION.—Except as provided in paragraph (1)(B), the specific identity of any chemical substance that is not on the confidential portion of the list published under section 8(b)(1) or subsequently added to the confidential portion of the list pursuant to this section shall not be eligible for protection from disclosure.~~

Commented [B38]: Addressed in subsection (d) clarifying that publicly available information cannot be claimed confidential.

"(6) BAN OR PHASE-OUT.—If the Administrator promulgates a ~~regulation~~ rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance—

"(A) any protection from disclosure provided under this section with respect to information relating to the chemical substance shall no longer apply; and

"(B) the Administrator promptly shall make the information public.

"(d) Requirements for Confidentiality Claims.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such ~~regulations~~ rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the ~~chemical identity~~information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law ~~in connection with 1 or more uses subject to this Act~~;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the conditions that—

"(i) the generic name shall—

"(I) conform with guidance prescribed by the Administrator under paragraph (3)(A); and

"(II) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(aa) that are considered to be confidential; and

"(bb) the disclosure of which would be likely to harm the competitive position of the person.

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

Formatted: Indent: Before: 0.5"

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in paragraphs (1) through (7) of subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the ~~regulations~~ rules promulgated and guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the information that has been submitted is true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a) shall be disclosed if—

"(1) the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of ~~human~~ health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) the Administrator determines that disclosure is necessary to protect ~~human~~ health or the environment;

"(4) the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, if—

"(A) 1 or more applicable agreements with the Administrator that conform with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; and

"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;

"(5) a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement shall conform with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable

basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee;

~~"(9) the information is publicly available; or~~ Commented [B39]: Addressed in subsection (d)

"(~~9~~10) the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION PROTECTED FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information that meets the requirements of subsection (d) for a period of 10 years, unless, prior to the expiration of the period—

"(i) an affected person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in subsection (g)(2).

"(B) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph (A), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph (A), a person reasserting the relevant claim shall submit to the Administrator a statement substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—

"(aa) review the request;

"(bb) make a determination regarding whether the information for which the request is made continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of not more than 10 years; or

"(BB) deny the claim.

"(C) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph (B), if the Administrator determines that the relevant statement under subparagraph (B)(ii)(I)—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection against disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Chemical Safety Improvement Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating ~~regulations~~ rules pursuant to section 6(d), subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d).

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection

from disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Chemical Safety Improvement Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) as necessary to comply with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(ii) if information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met; or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator on expiration of the period for appeal under subsection (g)(3), that has expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

"(B) DENIAL OR MODIFICATION.—

"(i) IN GENERAL.—Except as provided in subsections (c) and (f), the Administrator shall deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).

"(ii) REASONS FOR DENIAL OR MODIFICATION.—The Administrator shall provide to a person that has submitted a claim described in clause (i) a written statement of the reasons for the denial or modification of the claim.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection (b)(7), review all claims under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim under paragraph (1), the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

"(B) RELEASE OF INFORMATION.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

"(ii) EXCEPTIONS.—

"(I) IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to ~~human~~ health or the environment, in which case no prior

notification shall be necessary.

"(II) NO NOTIFICATION.—For information under paragraph (1), (2), (6), (7), or (9), ~~or (10)~~ of subsection (e), no prior notification shall be necessary.

Commented [B40]: No longer necessary with the clarification that publicly available information cannot be claimed confidential.

"(3) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(4) ADMINISTRATION.—In carrying out this subsection, the Administrator shall use the procedures described in part 2 of title 40, Code of Federal Regulations (or successor regulations).

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information submitted to the Administrator under this Act before the date of enactment of the Chemical Safety Improvement Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

"(2) PRIOR ACTIONS.—Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such ~~regulations~~ rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Chemical Safety Improvement Act.".

SEC. 16. PROHIBITED ACTS.

Section 15 of the Toxic Substances Control Act (15 U.S.C. 2614) is amended by striking paragraph (1) and inserting the following:

"(1) fail or refuse to comply with—

"(A) any ~~regulation~~ rule promulgated, consent agreement entered into, or order issued under section 4;

"(B) any requirement under section 5 or 6;

"(C) any ~~regulation~~ rule promulgated, consent agreement entered into, or order issued under section 5 or 6; or

"(D) any requirement of, or any ~~regulation~~ rule promulgated or order issued pursuant to title II;".

SEC. 17. PENALTIES.

Section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) is amended—

(1) in subsection (a)(1)—

(A) in the first sentence—

(i) by inserting "this Act or a ~~regulation~~ rule or order promulgated or issued pursuant to this Act, including" after "a provision of"; and

(ii) by striking "$25,000" and inserting "$37,500"; and

(B) in the second sentence, by striking" violation of section 15 or 409" and inserting "violation of this Act"; and

(2) in subsection (b)—

(A) by striking "Any person who" and inserting the following:

"(1) IN GENERAL.—Any person that";

(B) by striking "section 15 or 409" and inserting "this Act";

(C) by striking "$25,000" and inserting "$50,000"; and

(D) by adding at the end the following:

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of this Act, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

"(B) ORGANIZATIONS ~~AND ENTITIES~~.—An [organization ~~or entity~~] that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation.

Commented [B41]: Changes conforms this provision to other federal law.

"(3) KNOWLEDGE OF IMMINENT DANGER OR INJURY.—For purposes of determining whether a defendant knew that the violation placed another individual in imminent danger of death or serious bodily injury—

"(A) the defendant shall be responsible only for actual awareness or actual belief possessed; and

"(B) knowledge possessed by an~~other~~ individual may not be attributed to the defendant.".

SEC. 18. ~~PREEMPTION~~ STATE-FEDERAL RELATIONSHIP.

Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following:

"(a) In General.—

"(1) ESTABLISHMENT OR ENFORCEMENT.—Except as provided in subsections (c) and (d) **and subject to paragraphs (2) and (3)**, no State or political subdivision of a State may establish or continue to enforce [any of the following:~~[Legis. Counsel note: this phrase and the colon have been inserted here and in subsection (b) to comply with formatting conventions regarding the use below of provisions with headers.]~~]

"(A) TESTING AND INFORMATION COLLECTION.—A statute or administrative action to require ~~for~~ the development of information on a chemical substance or category of substances that is reasonably likely to produce the same information required under section 4, 5, or 6 in—

"(i) a rule promulgated by the Administrator;

"(ii) a testing consent agreement entered into by the Administrator; or

"(iii) an order issued by the Administrator.

"(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

"(i) ~~for a substance~~ found to meet the safety standard and consistent with the scope of the determination made under section 6; ~~[~~or~~]~~

"(ii) ~~for a substance~~ found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

"(C) SIGNIFICANT NEW USE.—A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

~~"(2) EFFECTIVE DATE FOR SCOPE OF CERTAIN PREEMPTION.—Under this subsection, Federal preemption **provided under paragraph (1)(B)** of State statutes and administrative actions applicable to specific substances shall be consistent with the scope of the **apply only to the uses or conditions of use of such substances that are included in the scope of the** safety determination made by the Administrator and **for the substance, and of any rule the Administrator promulgates pursuant to section 6(d).**~~

Commented [B42]: Moved to new subsection (c) below

"(3) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of State statutes and administrative actions applicable to specific substances shall not occur until the ~~date of the Administrator's determination that the substance meets the safety standard or until the date on which compliance with the rule issued under section 6(d) is required.~~ **effective date of the applicable action described in paragraph (1) taken by the Administrator.**

"(b) New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions.—Except as provided in subsections (c) and (d), no State or political subdivision of a State may establish (after the date of enactment of the Chemical Safety Improvement Act) **a**~~[any of the following:]~~

~~"(1) High priority.—A~~ statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance ~~identified~~ **designated** under section 4A, as of the date on which the Administrator commences a safety assessment under section 6.

~~"(2) Low priority.—A statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a low-priority substance identified under section 4A, as of the date on which the Administrator designates the substance as a low priority.~~

"(c) ~~EFFECTIVE DATE FOR~~ SCOPE OF PREEMPTION.— Federal preemption **under** subsections (a) and (b) of State statutes and administrative actions applicable to specific substances shall ~~be consistent with the scope of the~~ **apply only to the** chemical substances or category of substances subject to a rule or order, the **uses or conditions of use of such substances that are** identified by the Administrator as subject to review in a safety assessment and **included in the scope of the safety** determination made by the Administrator ~~and~~ **for the substance,** or **of any rule the Administrator promulgates pursuant to section 6(d).**

Commented [B43]: Modified to address scope of preemption under both (a) and (b).

"(d) Exceptions.—

"(1) ~~[IN GENERAL].—SUBSECTIONS~~ **IN GENERAL.—Subsections** (a) and (b) shall not apply to a ~~requirement, prohibition, or restriction~~ **statute or administrative action** of a State or a political subdivision of a State ~~that—[Legis. Counsel note: Generic header was added here and in paragraph (3) to ensure consistency with paragraph (2), which was given a header in client specs]~~ **applicable to a specific chemical substance that—**

"(A) is adopted under the authority of**, or authorized to comply with,** any other Federal law;

"(B) implements a reporting, monitoring, or **other** information collection ~~requirement~~ **obligation for the chemical substance** not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal ~~that—~~**, unless the~~at~~ action taken by the State or political subdivision of a State—**

~~"(i) does not impose~~**"(i) imposes** a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii) ~~is not otherwise required by or inconsistent with an~~ **(I) is already required by ~~an action~~a decision by the Administrator under section 5 or 6;** or

Formatted: Font: Not Bold

"(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that are included in the scope of a safety determination pursuant to section 6 or the scope of a significant new use rule promulgated pursuant to section 5, ~~**the same specific human health or environmental concern as an action taken by the Administrator under section 5 or 6**~~ **but is inconsistent with the action of the Administrator; or**

"(III) would cause a violation of the applicable action by the Administrator under section 5 or 6.

"(2) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—Nothing in this Act, nor any amendment made by this Act, nor any regulation, ~~requirement,~~ standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any regulation, ~~requirement,~~ standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

"(A) is adopted **under the authority of,** or authorized to comply with**,** any other Federal law;

"(B) implements **a** reporting, monitoring, or **other** information collection ~~requirement~~ **obligation for the chemical substance** not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal ~~that does not impose~~**, unless the~~at~~ action taken by the State or political subdivision of a**

State—

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance ~~and is not otherwise required by or inconsistent with an~~ **; and**

"(ii)(I) is already required by ~~an action~~a decision by the Administrator under section 5 or 6; or

Formatted: Font: Not Bold

"(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that are included in the scope of a safety determination pursuant to section 6 or the scope of a significant new use rule promulgated pursuant to section 5, ~~**the same specific human health or environmental concern as an action taken by the Administrator under section 5 or 6**~~ **but is inconsistent with the action of the Administrator; or**

"(III) would cause a violation of the applicable action by the Administrator under section 5 or 6.

"(3) APPLICABILITY TO CERTAIN RULES OR ORDERS.—Notwithstanding subsection (d) ~~[RULE OF CONSTRUCTION]. NOTHING CONSTRUCTION. N~~

"(A) nothing in this section shall be construed as ~~requiring the Administrator to modify or withdraw, any rule or order under section 5 or 6 of this Act, or as~~ modifying the effect ~~of~~under this section, as in effect immediately ~~as enacted~~ prior to [insert the effective date of the Chemical Safety Improvement Act], ~~of on~~ any rule or order promulgated or issued under this Act prior to [insert the effective date of the Chemical Safety Improvement Act]; and

Formatted: Indent: Before: 0.5"

"(B) with respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 6 prior to [insert the effective date of the Chemical Safety Improvement Act], this section as enacted prior to [insert the effective date of the Chemical Safety Improvement Act] shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after [insert the effective date of the Chemical Safety Improvement Act], unless the latter rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under section 4A(b) or (c) or as an additional priority for safety assessment and safety determination under section 4A(d).

Commented [B44]: Corrected typo

"(~~c~~d) Preservation of Certain State Law.—Nothing in this section shall be construed to preempt or otherwise affect any ~~warning requirement relating to consumer products or substances that is **statute or administrative** **action**~~ taken before January 1, 2015, under the authority of a State law, **that prohibits or** otherwise **restricts ~~chemical~~ manufacturing, processing, distribution in commerce, ~~or~~ use,** or disposal of a chemical substance. This subsection does not affect the relationship between state and federal law pursuant to any other federal law. ~~established pursuant to State law that was in effect on August 31, 2003, unless a rule, consent agreement, or order is promulgated under section 6 imposing a warning requirement, which shall preempt a chemical specific State warning requirement consistent with the scope of the Administrator's determination under section 6. **January 1, 2015**.~~

"(~~f~~e) State Waivers.—

"(1) IN GENERAL.—Upon application of a State or political subdivision of a State, the Administrator ~~may provide a waiver~~ **may—**

"(A) by rule, exempt from subsection (a) ~~and subsection (b)(1), regarding~~**, under such conditions as may be prescribed in the rule,** a statute or administrative action of that State or political subdivision of the State that relates to the effects **of,** or exposure to ~~any~~**, a** chemical substance under the ~~intended or reasonably anticipated~~ conditions of use **if** ~~if—~~

~~"(A)(i) the State or political subdivision of the State determines it cannot wait until the end of the period specified in the established schedule and deadline for the completion of a full safety assessment and determination established under section 3A; and~~

~~"(ii)~~ the Administrator determines that—

~~"(I)~~**"(i)** compelling State or local conditions warrant granting the waiver to protect ~~human~~ health or the environment;

~~"(II)~~**"(ii)** compliance with the proposed requirement of the State or political subdivision of the State ~~will~~ **would** not unduly burden interstate ~~and foreign~~ commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

~~"(III)~~**"(iii)** compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

~~"(IV)~~**"(iv)** based on the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is consistent with sound objective scientific practices, the weight of the evidence, and the best available science; **or**~~"(B)(i) the Administrator finds a safety assessment or determination has been unreasonably delayed; and~~

~~"(ii) the State certifies that —~~**"(B) exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the** ~~intended or reasonably intended~~ **conditions of use if the Administrator determines that—**

~~"(I)~~**"(i)** the State has a compelling local interest **that warrants granting the waiver** to protect ~~human~~ health or the environment;

~~"(II)~~**"(ii)** compliance with the proposed requirement of the State will not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

~~"(III)~~**"(iii)** compliance with the proposed requirement would not cause a violation of any applicable Federal law, rule, or order; and

~~"(IV)~~**"(iv)** the proposed requirement is grounded in reasonable scientific concern~~; or~~

~~"(C)(i) the State has contracted with the National Academy of Sciences to assess the hazard, use and exposure, and risk of a chemical substance;~~

~~"(ii) the report complies with the requirements of the Federal Advisory Committee Act Amendments of 1997; and~~

~~"(iii) based on the best available evidence described in the report of the National Academy of Sciences, the State establishes a requirement relating to the effects of or exposure to a chemical substance~~.

"(2) APPROVAL OF A STATE WAIVER REQUEST.—The Administrator shall grant or deny a waiver application—

"(A) not later than 180 days after the date on which an application under paragraph (1)(A) is submitted; and

"(B) not later than 90 days after the date on which an application under paragraph (1)(B) is submitted.

"(3) NOTICE AND COMMENT.—The application of a State or political subdivision of the State shall be subject to public notice and comment.

"(4) FINAL AGENCY ACTION.—The decision of the Administrator on the application of a State or political subdivision of the State shall be—

"(A) considered to be a final agency action; and

"(B) subject to judicial review.

"(5) DURATION OF WAIVERS.—A **waiver** ~~waiver—~~

~~"(A)~~ granted under paragraph **(1)(B)**~~(1)(A) shall remain in effect unless the waiver is found to be in conflict with a completed safety assessment and determination; and~~

~~"(B) granted under [subparagraph (B) or (C) of paragraph (2)]~~ shall remain in effect until **the later of—**

"(A) such time as the safety assessment and determination is completed**; and**.

~~"(6) Judicial review.—~~**"(B) the date on which compliance with an applicable rule issued under section 6(d) is required.**

~~"(A) In general.—Not~~**"(6) JUDICIAL REVIEW.—Not** later than 60 days after the date on which the Administrator makes a determination on an application of a State or political subdivision of the State under **subparagraph (A) or (B) of** paragraph (1), any person may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.

~~"(B) Judicial review of prioritization screening decision.—Not later than 60 days after the date on which the Administrator makes a decision on a recommendation made under section 4A(c) to designate a chemical substance as a low priority, the Governor of a State or a State agency with responsibility for protecting health and the environment that submitted the recommendation, as applicable, may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.~~

"(7) SAVINGS.—

"(A) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION FOR CIVIL

RELIEF OR CRIMINAL CONDUCT.—Nothing in this Act, nor any amendment made by this Act, nor any regulation, requirement, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall be construed to preempt, displace, or supplant any state or Federal common law rights or any state or Federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.

"(~~B~~) CLARIFICATION OF NO PREEMPTION.—Notwithstanding any other provision in this Act, nothing in this Act, nor any amendments made by this Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any state, maritime, or Federal common law or statutory theory.

Formatted: Indent: Before: 0.83"

"(~~B~~C) NO EFFECT ON PRIVATE REMEDIES.—

"(i) Nothing in this Act, nor any amendments made by this Act, nor any rules, regulations, requirements, safety assessments, safety determinations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.

"(ii) This Act does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, safety assessments, scientific assessments, or orders issued pursuant to this Act.".

SEC. 19. JUDICIAL REVIEW.

Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking "section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting "section 4(a), 5(d)(~~4~~), 6(c), 6(d), 6(g) or 8 of this title, or title II or IV of this chapter"; and

Commented [B45]: Conforming changes

(ii) in subparagraph (B), by striking "an order issued under subparagraph (A) or (B) of section 6(b)(1)" and inserting [~~"an regulation~~ order issued under this title"~~promulgated pursuant to section 6(d)"~~]; and

(B) in paragraph (2), in the first sentence, by striking "paragraph (1)(A)" and inserting "paragraph (1)"; and

(C) by striking paragraph (3); and

(2) in subsection (c)(1)—

(A) in subparagraph (B)—

(i) in clause (i)—

(I) by striking "section 4(a), 5(b)(4), 6(a), or 6(e)" and inserting "section

4(a), 5(d)~~(4)~~, ~~or~~ 6(d), or 6(g)"; and

(II) by striking "evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;" and inserting "evidence (including any matter) in the rulemaking record, taken as a whole; and"; and

(ii) by striking clauses (ii) and (iii) and the matter following clause (iii) and inserting the following:

"(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the ~~regulation~~rule, except as part of the rulemaking record, taken as a whole."; and

[(B) by striking subparagraph (C).]

SEC. 20. CITIZENS' PETITIONS.

Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an order under section 4 or 5(d)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "an order under section 4 or 5(d)"; and

(B) in paragraph (4), by striking subparagraph (B) and inserting the following:

"(B) DE NOVO PROCEEDING.—

"(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to promulgate a ~~regulation~~ rule pursuant to section 4, 5~~(d)~~, 6~~(b), 6(c), 6(d)~~, or 8 or an order issued under section 4 or 5~~(d)~~, the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.

"(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a ~~regulation~~ rule or order under section 4, the information available to the Administrator is insufficient for the Administrator to perform an action described in section 4, 4A, 5 or 6(d);

"(bb) in the case of a petition to issue an order under section 5(d), there is a reasonable basis to conclude that the chemical substance is not likely to meet the safety standard;

"(cc) in the case of a petition to initiate a proceeding for the issuance of a ~~regulation~~ rule under section 6(d), there is a reasonable basis to conclude that the chemical substance will not meet the safety standard;

or

"(dd) in the case of a petition to initiate a proceeding for the issuance of a ~~regulation~~ rule under section 8, there is a reasonable basis to conclude that the ~~regulation~~ rule is necessary to protect ~~human~~ health or the environment or ensure that the chemical substance meets the safety standard ~~from an unreasonable risk of harm to human health or the environment~~.

Commented [B46]: Conforming change

"(II) DEFERMENT.—The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

"(aa) the extent of the risk to ~~human~~ health or the environment alleged by the petitioner is less than the extent of risks to ~~human~~ health or the environment with respect to which the Administrator is taking action under this Act; and

"(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.".

SEC. 21. EMPLOYMENT EFFECTS.

Section 24(b)(2)(B)(ii) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by striking "section 6(c)(3)," and inserting "the applicable requirements of this Act;".

SEC. 22. STUDIES.

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.

SEC. 23. ADMINISTRATION.

Section 26 ~~(e) of the Toxic Substances Control Act (15 U.S.C. 2625(e)) is amended~~ **of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—**

(1) by striking subsection (b) and inserting the following:

"(b) Fees.—

"(1) IN GENERAL.—The Administrator shall establish, not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, by rule—

"(A) the payment of 1 or more reasonable fees as a condition of submitting a notice or requesting an exemption under section 5;

"(B) the payment of 1 or more reasonable fees by a manufacturer or processor that—

"(i) is required to submits a notice pursuant to the rule promulgated under section 8(b)(4)(A)(i) identifying a chemical substance as active;

Commented [B47]: Clarifies fee trigger

"(ii) is required to submits a notice pursuant to section 8(b)(5)(BE)(i) changing the status of a chemical substance from inactive to active;

"(iii) is required to report information pursuant to the rules promulgated under section 8(a)(4); and

"(iv) manufactures or processes a chemical substance subject to a safety assessment and determination ~~**designated by the Administrator as a high-priority substance**~~ **pursuant to section** 64A~~(b)~~**.**

Commented [B48]: Clarifies fee trigger

"(2) UTILIZATION AND COLLECTION OF FEES.—The Administrator shall—

"(A) utilize the fees collected under paragraph (1) only to defray costs associated with the actions of the Administrator—

"(i) to collect, process, review, provide access to, and protect from disclosure (where appropriate) information on chemical substances under this Act;

"(ii) to review notices and **make determinations for chemical substances under section 5**(d)(1) and ~~(c)~~**(3) and impose any**d **necessary restrictions under section 5(**d~~c~~**)(4);**

"(iii) to make prioritization decisions under section 4A;

"(iv) to conduct and complete safety assessments and determinations under section 6; and

"(v) to conduct any necessary rulemaking pursuant to section 6(d);

"(B) insofar as possible, collect the fees described in paragraph (1) in advance of conducting any fee-supported activity;

"(C) deposit the fees in the Fund established by paragraph (4)(A); and

"(D) not collect excess fees or retain a significant amount of unused fees.

"(3) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—In setting fees under this section, the Administrator shall—

"(A) take into account the cost to the Administrator of conducting the activities described in paragraph (2);

"(B) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

"(C) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to defray approximately 25 percent of the ~~**a portion of the**~~ **costs of conducting the activities identified in** ~~**that**~~ **paragraph** (2)(A)**, not to exceed** ~~**[____] percent of the cost of conducting the activities described in paragraph (2)(A)**~~$18 million, not including fees under subparagraph (E) of this paragraph;

Commented [B49]: Clarifies that cap on fees does not include fees to defray the full cost of assessment/determinations under section 4A(c).

"(D) ~~**establish appropriate criteria for manufacturers or processors that results in a proportionate assessment of fees**~~reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

"(E) for substances designated as additional priorities pursuant to section

4A(cd), establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the safety assessment and safety determination under section 6;

"(F) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) or subchapter III of chapter 5 of title 5, United States Code, ~~shall accrue~~ is applicable with respect to such meetings;

"(G) beginning with the fiscal year that is 3 years after the date of enactment of the Chemical Safety Improvement Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives, increase or decrease the fees established under paragraph (1) as necessary—

"(i) to ensure that funds deposited in the Fund are sufficient ~~and not more than reasonably necessary to defray the portion of the costs specified in subparagraph (C) of conducting~~ to conduct the activities identified in paragraph (2~~1~~)(A) and the full costs of safety assessments and determinations pursuant to subparagraph (E); and

Commented [B50]: Clarification

Formatted: Font: Not Bold

"(ii) to account for inflation;~~; and~~

~~"(iii) to minimize, to the maximum extent practicable, shortfalls in or an accumulation of unused amounts in the Fund established by paragraph (4)(A);~~

"(H) adjust fees established under paragraph (1) as necessary to vary on account of differing circumstances, including reduced fees or waivers in appropriate circumstances, to reduce the burden on manufacturing or processing, remove barriers to innovation, or where the costs to the Administrator of collecting the fees exceed the fee revenue anticipated to be collected; and

"(I) if a notice submitted under section 5 is refused or subsequently withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

"(4) TSCA IMPLEMENTATION FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the 'TSCA Implementation Fund' (referred to in this subsection as the 'Fund'), consisting of—

"(i) such amounts as are deposited in the Fund under paragraph (2)(C); and

"(ii) any interest earned on the investment of amounts in the Fund; and

"(iii) any proceeds from the sale or redemption of investments held in the Fund.

"(B) CREDITING AND AVAILABILITY OF FEES.—

"(i) IN GENERAL.—Fees authorized under this section shall be collected and

available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation.

"(ii) REQUIREMENTS.—Fees collected under this section shall not—

"(I) be made available or obligated for any purpose other than to defray the costs of conducting the activities identified in paragraph ~~(24)~~(A);

"(II) otherwise be available for any purpose other than implementation of this Act; and

"(III) so long as amounts in the Fund remain available, be subject to restrictions on expenditures applicable to the Federal government as a whole.

"(C) UNUSED FUNDS.—Amounts in the Fund not currently needed to carry out this ~~paragraph~~ subsection shall be—

"(i) maintained readily available or on deposit;

"(ii) invested in obligations of the United States or guaranteed by the United States; or

"(iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

"(D) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2015) of the Office of Pollution Prevention and Toxics of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for covered functions for fiscal year 2015 (excluding the amount of any fees appropriated for the fiscal year).

"(5) AUDITING.—

"(A) FINANCIAL STATEMENTS OF AGENCIES.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of an executive agency.

"(B) COMPONENTS.—The annual audit required under sections 3515(b) and 3521 of that title of the financial statements of activities under this subsection shall include an analysis of—

"(i) the fees collected under paragraph (1) and disbursed;

"(ii) compliance with the deadlines established in section 6 of this Act;

"(iii) the amounts budgeted, appropriated, collected from fees, and disbursed to meet the requirements of sections 4, 4A, 5, 6, 8, and 14, including the allocation of full time equivalent employees to each such section or activity; and

"(iv) the reasonableness of the allocation of the overhead ~~allocation of costs~~ associated with the conduct of the activities described in paragraph (~~2~~1)(A).

"(C) INSPECTOR GENERAL.—The Inspector General of the Environmental Protection Agency shall—

"(i) conduct the annual audit required under this subsection; and

"(ii) report the findings and recommendations of the audit to the Administrator and to the appropriate committees of Congress.

"(6) TERMINATION.—The authority provided by this section shall terminate at the conclusion of the fiscal year that is ~~[10/15]~~ years after the date of enactment of the Chemical Safety Improvement Act, unless otherwise reauthorized or modified by Congress."; ~~and~~

(2) in subsection (e), by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services"; and

(3) adding at the end the following:

"(h) Prior Actions.—Nothing in this Act requires the Administrator to modify or withdraw any rule or order promulgated or issued pursuant to this Act before the date of enactment of the Chemical Safety Improvement Act.".

.

SEC. 24. DEVELOPMENT AND EVALUATION OF TEST METHODS.

Section 27(a) of the Toxic Substances Control Act (15 U.S.C. 2626(a)) is amended in the first sentence by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

SEC. 25. STATE PROGRAMS.

Section 28 of the Toxic Substances Control Act (15 U.S.C. 2627) is amended—

(1) in subsection (b)(1)—

(A) in subparagraphs (A) through (D), by striking the comma at the end of each subparagraph and inserting a semicolon; and

(B) in subparagraph (E), by striking ", and" and inserting "; and"; and

(2) by striking subsections (c) and (d).

SEC. 26. AUTHORIZATION OF APPROPRIATIONS.

Section 29 of the Toxic Substances Control Act (15 U.S.C. 2628) is repealed.

SEC. 27. ANNUAL REPORT.

Section 30 of the Toxic Substances Control Act (15 U.S.C. 2629) is amended by striking paragraph (2) and inserting the following:

"(2)(A) the number of notices received during each year under section 5; and

"(B) the number of the notices described in subparagraph (A) for chemical substances subject to a ~~regulation~~rule, testing consent agreement, or order under section 4;".

SEC. 28. EFFECTIVE DATE.

Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601 note; Public Law 94–469) is amended by striking "Except as provided in section 4(f), this" and inserting "This".

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 7/27/2015 2:40:46 PM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
Subject: FW: BNA article
Attachments: TSCA Reform Legislation and Its Workability. Thoughts on Steps to Help Ensure (00162952)-1.pdf

Have you seen this?

BNA Insights

TSCA

CONGRESS

Competing proposals are working their way through the House and Senate to amend the Toxic Substances Control Act, the nation's primary law for managing chemicals in commerce. In this article, former senior Environmental Protection Agency officials Charles Auer and James Aidala and attorney Lynn Bergeson discuss making the bill clearer and how congressional direction can be provided on what EPA is to do with certain new provisions to implement them in the first years of any amended TSCA.

TSCA Reform Legislation and Its Workability: Thoughts on Steps to Help Ensure Successful Implementation at the Outset and Over Time

BY CHARLES M. AUER, JAMES V. AIDALA, JR., AND LYNN L. BERGESON

Introduction

"Congress On the Verge of Amendments to TSCA," and headlines of similar ilk are not what those of us who daily engage with Toxic Substances Control Act (TSCA) issues thought we would ever see. At the same time, there is an element of "now what" since the legislative sausage grinder continues to churn and there are competing proposals for "TSCA reform" from the House and Senate.

Charles M. Auer is President of Charles Auer & Associates, LLC. Mr. Auer was formerly the Director of the U.S. Environmental Protection Agency's (EPA) Office of Pollution Prevention and Toxics (OPPT) from September 2002 to January 2009.

James V. Aidala, Jr., is a Senior Government Consultant with Bergeson & Campbell, P.C., Washington, D.C. He served as assistant administrator for the Office of Prevention, Pesticides, and Toxic Substances, now the Office of Chemical Safety and Pollution Prevention, under the Clinton administration from 2000 until 2001.

Lynn L. Bergeson is Managing Partner of Bergeson & Campbell, P.C. and practices extensively in all matters involving the Toxic Substances Control Act and related global chemical notification programs.

The views expressed in this article are entirely those of the authors.

This article is not an analysis of the politics between the House and Senate bills or a prognostication about which version of the legislation will be used to fashion final legislation or the prospects for ultimate passage. Instead, the authors are past senior officials in the U.S. Environmental Protection Agency (EPA) toxics regulatory program and an attorney with decades of experience as a TSCA practitioner. As such, we believe we can offer some additional perspective on what we believe is a missing element in the current TSCA legislative debate: given the legislative provisions on both sides of Capitol Hill, what are some of the key elements that perhaps could use more, or certainly clearer, congressional direction about what EPA is to do with certain new provisions to implement them in a timely and relatively efficient manner over the first years of implementation of any amended TSCA.

With all due respect to the dedicated members of Congress who have put serious time and energy into TSCA reform, and especially the staff of these members and committees, there appears to be somewhat of a missing perspective from those who have had past work experience in a federal regulatory agency. The lack of an Obama administration bill has also led to a void in offering detailed programmatic suggestions; although it appears that EPA has been active in offering regular "technical advice," often such advice has certain limitations in how much or how loud programmatic considerations can be made.

We offer here some thoughts for our EPA colleagues and other interested parties who now can and will be more actively engaged in the discussions about how best to move forward. We may have opinions about how

certain provisions should have been crafted, but we take as a starting point the House-passed bill (H.R. 2576) and S. 697 as reported by the Senate Environment Committee.

Given that those two proposals will drive the discussion between the two chambers, we pose some questions and offer some suggestions that we believe would enhance the chances for implementation success as the debate moves forward. Mostly, this can be summarized as a quest to determine "how does it work" when examining the competing proposals, and identify specific areas where Congress might offer more clarity, or where our EPA colleagues might benefit from more explicit provisions or definitions (or at least expectations).

Currently, many new terms, some with uncertain or missing definitions, along with what we see as impractical (yet perhaps politically important) directives could result in litigation, delay, and general hindrance to what appears to be shared hopes for programmatic success.

In addition, some of the authors here collaborated on an earlier August 2010 treatise requested by the American Bar Association Section of Environment, Energy, and Resources of laying out programmatically practical advice as a set of recommendations regarding TSCA reform.[1]

Discussion of Workability Issues

As discussed below, there are a number of what we refer to as "workability" issues that, in a perfect world, Congress would address and clarify, or EPA would suggest to Congress to make appropriate revisions and clarifications to ensure implementation success. While there are more that could be added to this list, we note key ones below.

Need for Greater Definitional and Legal Clarity

The bills use a number of new terms and concepts that lack clarity. While we understand the potential role of ambiguity to help legislators come to agreement, we are also alert to the potential for lawsuits challenging EPA's interpretation of the terms' meaning and intent in the absence of clear drafting or congressional clarification and explanation. Provisions of the 1990 Clean Air Act Amendments are hotly debated almost 30 years after Congress spoke; perhaps here Congress can speak more clearly. Regarding the current TSCA bills, examples include:

- "Significant hazard" and "significant exposure" as used in S. 697 Section 4A(b)(3) concerning EPA identification of high-priority substances. The former term is new and not further explained while the latter is somewhat similar to the term "significant or substantial human exposure" that appears in current TSCA Sections 4(a) and 5(e) regarding "exposure-based actions." While EPA has released TSCA policy statements regarding its interpretation of "significant or substantial human exposure," the different phrasing and the broadening of the term to encompass both human *and environmental* exposure raise questions about the intended meaning. It would be helpful if the legislative intent/meaning of these terms was better defined or at the least clarified.
- "May present an unreasonable risk" in H.R. 2576 Section 6(b)(3)(A), which concerns EPA's determination of chemicals requiring a risk evaluation. This term, which appears without elaboration in current TSCA Sections 4(a) and 5(e), is modified in H.R. 2576 by the addition of an explanatory "because" phrase:
  may present an unreasonable risk . . . *because of potential hazard and a potential route of exposure under the intended conditions of use.*
  The additional phrase changes the meaning of "may present an unreasonable risk" in ways that are likely to lead to legal challenges and would benefit from clarification and explanation should it be retained. To facilitate implementation, it might be preferable to eliminate it. We question in particular the legal and policy implications of the entirely open-ended phrase "a potential route of exposure." By the fact of their presence in commerce, all chemicals have "a potential route of exposure." The House Report on H.R. 2576[2] does not offer any additional explanation of the phrase but reinforces our concern when it states that "[t]he standard for making this determination is broad and flexible because its application precedes the detailed scientific risk evaluation that it triggers." While we agree that the preliminary assessment needs to be "broad and flexible," in our view this meaning would be assured by using the unadorned phrase "may present an unreasonable risk," while perhaps also retaining "under the intended conditions of use" given the role this phrase plays in the text.
  Is it the intent of this change to devolve "may present an unreasonable risk" to a "broad and flexible" hazard-based requirement for the purpose of determining chemicals that are in need of a risk evaluation? This is one plausible interpretation, but the existence of many others suggests this language needs to be revised or clarified.
- Similarly mischievous is the definition of "potentially exposed subpopulation" in the H.R. 2576 definitions section that explicitly centers on those with "greater potential exposure"—a definition which strikes us as quite broad. For example, a routine occupational exposure is likely to be "greater" such that normal worker exposures that are otherwise subject to oversight by the Occupational Safety and Health Administration (OSHA) seem to satisfy the definition. It is unclear whether the intent is that workers' exposure to chemicals is sufficient to trigger application of vulnerable population considerations found later in the bill, recognizing that this would apply such consider-

[1] *See* the American Bar Association Section of Environment, Energy, and Resources Special Committee on TSCA Reform, *Practical Advice for TSCA Reform: An Insider Perspective*, J. Aidala, C. Auer, L. Goldman, M.D., and J. Gulliford (Aug. 2010) (ABA Report), available at http://www.americanbar.org/content/dam/aba/administrative/nr/projects/tsca_reform/whitepapers/practical_advice_for_tsca_reform.authcheckdam.pdf.

[2] H.R. Report No. 114-176, at 24 (2015).

  DEN ISSN 1060-2976

ations in theory to all TSCA chemicals. Is this an intent to shift regulation of workplace exposure to chemicals from OSHA to EPA? Similarly, the definition here would incorporate any "group of individuals within the general population" with "greater potential exposure" as a special subpopulation, which strikes us as irrational since mathematically, in virtually all cases, some part of the population will have a "greater" exposure or otherwise exposures calculated as "above average" (the Lake Wobegon effect?). Somewhat mitigating our concern is the careful drafting elsewhere in the text where the term appears (Section 6(a)[3] regarding scope of regulation and Section 6(b)(6)[4] concerning determinations of no unreasonable risk) that can be read to suggest a more nuanced reading of the term. The House Report on H.R. 2576 also states that "[i]t is the Committee's intention" that EPA "be clear about who is being identified and the basis for such a decision when invoking provisions involving subpopulations."[5] We also note that the definition of this term in S. 697 expressly limits its application to groups "identified" by EPA, a somewhat different approach that we find clear and one that could also reduce the potential for legal challenges relative to the approach in H.R. 2576. It is clear that Congress recognizes the importance of ensuring consideration of vulnerable populations, but an overly broad application of the concept will inevitably dilute the provision's effect while also inviting legal challenges and other implementation hurdles.

- The requirements in S. 697 Section 4A(b)(4) that EPA must meet in identifying low-priority substances. The current text outlines a process whereby EPA, in identifying low-priority chemicals, must conclude "[it] has information sufficient to establish that the chemical substance is likely to meet the safety standard." Report Number 114-67 prepared by the Senate Environment and Public Works Committee indicates that it "intends that EPA adequately justify prioritization decisions, which it should fully describe" when seeking comment on the proposed designation.[6] The ABA Report explored the issue of "numbers" starting with the observation that there are over 80,000 chemical substances listed on the TSCA Inventory. The ABA Report then suggests, following the application of several assumptions and facts, that as many as 4,300 chemicals may require some type of control action under an amended TSCA.[7] Even if this analysis is off by a factor of two or three, it suggests that somewhere around 30,000 chemicals are potential low-priority candidates. This rough analysis suggests that EPA could confront the almost impossible burden of satisfying the low-priority identification requirements for many thousands of chemicals, or be required to put them into the safety assessment and safety determination process, which would be a prodigious undertaking. If EPA cannot triage and thereby manage its work in the first and subsequent years of any revised program, the expectation that tens of thousands of chemicals need some significant level of assessment effort will continue to hinder program effectiveness for another 40 years.

In addition, the provisions in S. 697 concerning Section 8 exposure information reporting by manufacturers and processors and the ability to require (under Section 4) "limited testing" needed for prioritization would appear substantially to improve our knowledge of chemicals and their potential for risk. It is unclear to us, however, whether the exposure information and the level of testing that can be required for prioritization purposes are sufficient to meet the legal requirements inherent in "*conclud[ing it] has sufficient information to establish* that the chemical substance is likely to meet the safety standard." If such test data and exposure information were insufficient to support the required conclusion, EPA would confront both a fundamental issue in its implementation of the bill's requirements and the possible need to take very large numbers of chemicals into some kind of Section 6 safety assessment and determination process. Couple this scenario with the fact that low-priority identifications would also be subject to judicial review, the combination could prove programmatically disastrous for EPA.

This is a huge workability issue. We encourage careful drafting to capture what Congress wants EPA to do to ensure that the legal requirements imposed on EPA in identifying low-priority chemicals are carefully matched with the types and level of test data and exposure information that are likely to be available for TSCA regulated chemicals under the new legislation.

These are but a few of the many areas that would benefit from greater definitional and legal clarity.[8] While we might have our own ideas about how such clarity might be achieved, our point here is to hope and encourage EPA to be actively involved, carefully evaluate the programmatic implications, and provide an explicit (and perhaps occasionally unpleasant) reality check with the congressional sponsors to help ensure that Congress is clear about what it expects of EPA and its toxics program. EPA officials could offer remedies in the form of suggested report language, recommended statutory clarity, or interpretative memoranda for the record in an attempt to avoid some of the likely implementation challenges posed by the existing language, among other options.

---

[3] S. 697, Section 6(a) states: "[S]o that the chemical substance or mixture no longer presents or will present an unreasonable risk, including an *identified unreasonable risk* to a potentially exposed subpopulation." (Emphasis added.)

[4] S. 697, Section 6(b)(6) states: "The Administrator shall not make a determination under this subsection that a chemical substance will not present an unreasonable risk of injury to health or the environment if the Administrator *determines* that the chemical substance, under the intended conditions of use, presents or will present an unreasonable risk of injury to 1 or more potentially exposed subpopulations." (Emphasis added.)

[5] H.R. Report No. 114-176, at 22.

[6] S. Report No. 114-67, at 11-12 (2015).

[7] ABA Report at 6. The assumptions include that only 50 percent of the Inventory chemicals are currently in commerce and that EPA's regulatory experience with TSCA new chemicals offers some perspective on existing chemical actions, and the fact that, based on then current reporting (reference 2006 CDR), approximately 6,200 non-polymeric chemicals are in commerce above 25,000 pounds/year at a site.

[8] We offer much more information on pending TSCA reform bills and detailed critical analyses of these measures at the Bergeson & Campbell, P.C. website under TSCA Reform, http://www.lawbc.com/regulatory-developments/tsca-reform.

Need for a Transition Period

One approach to avoid some of the issues identified here could be to include some kind of ramp-up or transition period with carefully crafted deadlines for various phases of initial programmatic implementation. We have identified a number of potential timing conflicts or issues in the bills that should be considered and potentially revised to ensure a smooth and effective start and ongoing implementation of the new requirements. The issues we have identified include the following:

- S. 697 Section 3A(b) imposes a two-year deadline on EPA to develop through notice and comment rulemaking policies, procedures, and guidance (PP&Gs) as necessary to implement Sections 4, 4A, 5, and 6 (concerning testing, prioritization, new chemicals, and existing chemicals, respectively). H.R. 2567 Section 26(k)(1) also imposes a two-year deadline after enactment to develop PP&Gs needed to implement provisions affected by the bill.
- It is unclear how the two-year deadline for PP&Gs in S. 697 can be consistent with Section 4A(a)(1) that imposes a one-year deadline for establishing by rule a risk-based screening process for distinguishing between high- and low-priority chemicals, nor how either of these provisions squares with the requirement at Section 4A(a)(2) that EPA release an initial priority list within 180 days.
- These deadlines and requirements then flow into other S. 697 deadlines that, given the effort that will be required to meet the PP&G notice and comment requirements, raise questions whether it is reasonable that, within three years after enactment, EPA could also have started or completed safety assessments on 20 high-priority chemicals as S. 697 Section 4A(a)(2)(C) requires. Similarly, it is difficult to have confidence in meeting both the two-year deadline under Section 8(a)(4) for promulgating reporting rules to obtain information to carry out Sections 4 and 6 with the three-year safety assessment deadline.
- Regarding control actions under Section 6, H.R. 2567 requires that EPA propose a Section 6(a) regulation within one year after completing the risk evaluation with a final rule to be issued within two years. S. 697 would also give EPA two years to complete a Section 6(d) control rule. Even with the availability of extensions, the timelines strike us as tight, which invites litigation and/or seemingly random spasms of programmatic attempts to comply with difficult deadlines.

The ABA Report recommends six to 18 months to allow EPA to devise new policies and procedures and engage stakeholders and the scientific community. It also notes that standard Administrative Procedure Act (APA) notice and comment rulemaking takes at least two years and generally much longer. The ABA Report also states that one significant oversight in drafting the Food Quality Protection Act[9] was the absence of a transition time for EPA and industry in meeting requirements for pesticides under the old and new standards. Congress may wish to look carefully into these aspects and consider both an initial transition period or a phase-in period for the new requirements. Deadlines for specific requirements could be carefully crafted to impose measured and attainable demands on EPA and stakeholders during the critical early years of implementation. Deadlines should be designed to build the programmatic and regulatory infrastructure in a way that is logical, sustainable, and workable. In considering this question, it is important to recognize the scope differences between the two bills. Both bills offer different approaches and the selection of the most suitable approach should be guided by scoping considerations, not *ad hoc* "picking and choosing" indiscriminately. We offer our thoughts about a possible approach under a scenario including all of the major elements contained in both bills.

A "transition period" after enactment would allow EPA to begin to staff up, secure suitable contracts and get them in place, articulate clearly what the law requires and accordingly respond programmatically, and hear from and engage with stakeholders while beginning efforts to develop policies and approaches under new legislation. This ramp-up period is critically important in ensuring EPA's legal, policy, and organizational frameworks are solid and well grounded. As one example of how such a transition period might work, we have two specific suggestions to offer concerning aspects that would not come into force during this initial period, nor for some time afterward:

- The current approach to new chemicals in TSCA Section 5 should be retained for some period after enactment. This would avoid undue disruption and provide a transition period that could last until EPA had developed any needed rules and PP&Gs to apply the new Section 5 requirements. This transition period could be shorter or longer in duration. From our perspective, there would be value in a longer transition period that would free up EPA and stakeholder legal, technical, and policy resources to focus on other early implementation tasks.
- New requirements that appear in S. 697 Section 14 (such as those in subsections (f) and (g) regarding the development of a unique identifier and a 90-day deadline for EPA review of new confidential business information (CBI) claims, respectively) should be delayed and enter into effect at some later date. This date might coincide with the entry into force of the new Section 5 requirements. This delay would not affect the entry into force of the provision in both bills that requires substantiation of CBI claims for new submissions.

We recognize that the staging of requirements during a multi-year phase-in period could take a number of possible forms depending on the specific contextual needs and realities presented by final language approved by Congress. We encourage EPA to share its thinking to help inform Congress about what EPA believes would be workable and effective in ensuring a smooth launch of the new authorities available to it. For purposes of illustration, Table 1 offers one possible phase-in scenario that would help to build and apply the programmatic and regulatory infrastructure over time

[9] Pub. L. No. 104-170, 7 U.S.C. §§ 136 *et seq.*

DEN ISSN 1060-2976

in a way that we believe is both workable and logical. In all cases, the deadlines suggested are after enactment. We fully acknowledge that "it is easy for us to say" from an external vantage point, but our message is that successful implementation in the long run will be much affected by successful early construction of any revised toxics program.

Table 1. Illustrative Multi-Year Phase-in Approach

Deadline	Phased-in Requirements
15 months	■ Promulgate S. 697 Section 8(b)(4) Inventory reset reporting rule. Although the involvement of processors as proposed in S. 697 brings challenges, the scope of reporting is limited and straightforward. Assuming a six-month reporting period and electronic reporting, the information should be available to inform the first prioritization as proposed below.
18 months	■ Issue final PP&Gs for S. 697 Section 4A prioritization screening process for high- and low-priorities.
24 months	■ First implementation by EPA of the prioritization screening process to create an initial priority list using available information. ■ Promulgate S. 697 Section 8(a)(4) reporting rules and issue any needed PP&Gs. This provision relates to information needed to carry out Sections 4 and 6; we note that S. 697 Section 4A should also be referenced in this provision, recognizing the role of exposure information in prioritization screening.
30 months	■ Promulgate Section 4 and Section 6 PP&Gs. ■ Promulgate any needed Section 5 reporting rules and PP&Gs after which the new regulatory regime would apply to Section 5 notifications and exemption requests. ■ S. 697 Section 14 requirements for timely EPA review of CBI claims and development of a unique identifier could enter into effect at the same time as the new Section 5 requirements.
36 months	■ EPA releases second prioritization list. This timing should allow EPA to consider the results from early actions to require limited testing for prioritization under S. 697 Section 4(a)(2) as well as Section 8(a)(4) reporting by manufacturers and processors.

After urging Congress to exercise restraint in its deadlines, we offer one suggestion that goes against this advice. We see merit in requiring that the Science Advisory Committee on Chemicals (SACC; as proposed in S. 697 Section 3A(j)) be established by EPA six months (rather than one year) after enactment. From our perspective, this would ensure that the SACC is available as an early resource to advise EPA in developing PP&Gs and needed rulemakings. We note that EPA's recent announcement of the formation of a Chemical Safety Advisory Committee (CSAC) offers a potential starting point upon which these efforts could be built.[10] The June 12, 2015, announcement of the CSAC encouraged us to suggest the earlier deadline.

The bills would impose a number of complex and overlapping requirements on EPA that unless carefully staged would challenge both the agency and stakeholders. Recognizing that, politically speaking, "speed is of the essence" to those seeking to revitalize the toxics program, suggestions for transition periods and phased-in requirements might seem undesirable. While we support our suggestions as being consistent with the desire for early implementation success, another avenue of acceleration for the numerous rulemakings and requirements for PP&Gs about many new definitions and program components could be explicit legislative truncating of the rulemaking process. Congress could explicitly remove some or all early program activities from the Office of Management and Budget (OMB) review requirements (and the underlying legislative mandates) either on a selective basis or for some defined initial period of time (such as the first three years after enactment to ease early implementation). We raise what some might see as an alarming suggestion only to illustrate how difficult the current legislation will be to implement unless more attention is paid to the programmatic meshing of the underlying wheels and bearings (and, metaphorically, to avoid the program from grinding to a halt).

Establishing Fees

As OPPT has no experience with fee setting and collecting (except for the $2,500 premanufacture notification (PMN) fee), the provisions in Section 26 for establishing a TSCA fee system seem unrealistic. The promulgation deadline is one year from enactment to establish fees, after having met with parties potentially subject to fees, and to meet every three years thereafter regarding fees. Much greater direction from Congress is needed to have this rather critical component of a new TSCA program get off the ground smoothly.

At least two suggestions can be found from the pesticide program. First, there is in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) a requirement for a "maintenance fee," which is a fee imposed on each registered product in EPA's system. The fee is uniform, but capped for companies with large numbers of products, and exemptions are made for small businesses. Such a fee might be imposed by anyone required to submit certain reports under Section 8 (such as reports of "active" chemicals under the Inventory reset provision (S. 697 Section 8(b)(4) and manufacturer/processor reporting under S. 697 Section 8(a)(4)). Second, there is a fee for those who submit applications for pesticide registration; here the concept is that fee rates

[10] 80 Fed. Reg. 33,517 (June 12, 2015).

reflect some measure of the differing need for more scientific review and evaluation by EPA depending on the nature of the submitted application. The more review needed, the higher the fees that are imposed.

The maximum fee for a submitted package, one which requires review of an extensive data set of more than 100 health and environmental toxicity studies, is close to $1 million. What this also reveals is that the pesticide program has a refined estimate of what it takes for EPA personnel to review various toxicity studies and exposure/use information according to EPA procedures and risk assessment guidelines. That information could be used to craft a fee scheme that could be presented to Congress for consideration as a way to facilitate the establishment of a fee system to more rapidly supply the resources to the chemical assessment program.

Recognizing that it will take time to set up a fee schedule by rule, another concept is to establish an interim fee scheme. This could include additional fees on chemical notification submissions under Section 5. Alternatively or in addition, Section 4 or Section 8 submissions could include a fee requirement to offset program costs to whatever extent Congress requires that fees contribute to EPA's program needs.

Addressing Persistent, Bioaccumulative, and Toxic Chemicals (PBT)

Both bills address PBTs, but in very different ways. S. 697 Section 4A(a)(2)(B)(iii) requires that EPA, in identifying high-priority substances, "shall give preference to chemical substances scored as high for persistence and bioaccumulation," while Section 6(d)(2)(B) requires that EPA select prohibitions and other restrictions for PBTs that EPA determines "are sufficient to ensure that the chemical substance meets the safety standard, reduce exposure to the substance to the maximum extent practicable."[11] H.R. 2576 Section 6(i) outlines a more elaborate and focused program mandating that no later than nine months from enactment, EPA must publish a list of chemicals that the "Administrator has a reasonable basis to conclude are persistent, bioaccumulative, and toxic," excluding metals and chemicals subject to Section 6(e) critical use exemptions. No reference or guidance is provided in statutory text regarding the criteria to be applied in developing this list, although the Committee Report states that the Committee "hopes" EPA will rely on the 2012 Work Plan Chemicals Method Document.[12] Within two years of enactment, EPA is to designate as a PBT chemical of concern chemicals "with respect to persistence and bioaccumulation, scores high for one and either high or moderate for the other," pursuant to the 2012 TSCA Work Plan Chemicals Methods Document, *and* "exposure to which is likely to the general population or to a potentially exposed subpopulation." Section 6(i)(3) then requires "expedited action" within two years of designation (subject to the availability of appropriations) to "reduce likely exposure to the extent practicable" (an off-ramp is available if certain steps occur following publication of the initial list). The "availability of appropriations" language seems to be a tacit acknowledgment of the impossibility of meeting these strenuous deadlines.

The Senate version strikes us as a more sensible deployment of resources and avoids the "death by listing" that could arise under H.R. 2576. Fears of market deselection pressure would also provide an incentive for any manufacturer to pursue continuous litigation over each step of any selection or evaluation proposal. We are also concerned about the effect of the somewhat open-ended concept of "likely exposure" in designating a PBT chemical of concern and in mandating control requirements for the reasons noted above as the lack of clarity in this standard could both invite unnecessary restrictions and lawsuits.

Emerging Technologies and Other Issues

Neither bill addresses the growing problem of how best to support and regulate chemicals that are products of emerging technologies such as biotechnology, nanotechnology, or synthetic biology. This issue crystallized with ironic clarity on July 2, 2015, when the White House Office of Science and Technology Policy (OSTP), OMB, the U.S. Trade Representative, and the Council on Environmental Quality issued a memorandum directing EPA, the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) to update the Coordinated Framework for the Regulation of Biotechnology. Last updated in 1992 and first rolled out in 1986, the Coordinated Framework outlines a comprehensive federal regulatory policy for products of biotechnology. The July memorandum directs the federal agencies to develop a long-term strategy to ensure that the regulatory system for biotechnology products is prepared for future products, and commissions an expert analysis of the future landscape of biotechnology products. A July 2, 2015, OSTP blog[13] item notes that the complexity of the array of regulations and guidance documents developed by EPA, FDA, and USDA "can make it difficult for the public to understand how the safety of biotechnology products is evaluated, and navigating the regulatory process for these products can be unduly challenging, especially for small companies." The memorandum states that the objectives "are to ensure public confidence in the regulatory system and to prevent unnecessary barriers to future innovation and competitiveness by improving the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products while continuing to protect health and the environment."

The Coordinated Framework describes the federal regulatory policy intended to ensure the safety of biotechnology products. The 1992 update to the Coordinated Framework "sets forth a risk-based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment." Accord-

[11] It is noteworthy that the Senate bill references in Section 6 (prioritization screening) the "October 2014 TSCA Work Plan and subsequent updates," which suggests to us that Congress expects EPA to issue both Work Plan *and* prioritization lists.

[12] TSCA Work Plan Chemicals: Methods Document (Feb. 2012), available at http://www.epa.gov/oppt/existingchemicals/pubs/wpmethods.pdf.

[13] *See* "Improving Transparency and Ensuring Continued Safety in Biotechnology," available at https://www.whitehouse.gov/blog/2015/07/02/improving-transparency-and-ensuring-continued-safety-biotechnology.

  DEN ISSN 1060-2976

ing to the memorandum, the update affirmed that federal oversight should focus on the characteristics of the product and the environment into which it is being introduced, rather than the process by which the product is created.[14] This last point appears to reaffirm one of the central tenets of the 1986 Coordinated Framework—that the premise is to "regulate the risks of the product, not the process" used to derive novel substances.

Modernizing the Coordinated Framework is as critically important as modernizing TSCA. Despite the significant role TSCA plays in the U.S. regulatory system for products of biotechnology, curiously there has been virtually no discussion of or attention given to TSCA's application to products of biotechnology during congressional deliberations on either bill. That the modernizing of the Coordinated Framework will occur on a separate trajectory perhaps in parallel with implementing TSCA reform legislation should it happen this year poses both risks and opportunities.

That the Coordinated Framework needs a do over is clear. A number of recent reports have convincingly outlined the reasons why the Coordinated Framework can no longer nimbly, clearly, or comprehensively regulate products on biotechnology and call for exactly what the Administration is undertaking.[15]

The Administration's decision to modernize the Coordinated Framework is welcome news. If TSCA reform legislation is enacted this year, the tricky part will be ensuring the modernizing of TSCA and the modernizing of the Coordinated Framework are aligned. If TSCA reform legislation does not advance this year, it will be interesting to see how the two initiatives progress in tandem.

Similar issues and questions arise with regard to the treatment of the products of nanotechnology under a modernized TSCA. While there is no ongoing review of the government's approach, the fact that EPA has received over 170 TSCA new chemical notifications for new nanoscale chemical substances in the past ten years is noteworthy of significant innovation in this area. Similarly, the fact that EPA has been struggling with a TSCA Section 8(a) rule with respect to nanoscale versions of existing chemical substances for over seven years indicates that this is an area of intense agency attention and considerable legal and policy challenge.

While we do not wish to delay or complicate the current progress being made in advancing bills to modernize TSCA, we believe that it is *important* that Congress consider the issues associated with emerging technologies in the context of revising TSCA so as to ensure protection of health and the environment while also ensuring that the U.S. continues its global leadership in the science and commercial development of the products of these technologies. We would also lend our voice to that of others who have recommended that Congress not forget about changes to TSCA that are needed to meet legal obligations under the Stockholm and Rotterdam Conventions concerning persistent organic pollutants (POP) and prior informed consent (PIC), respectively, thereby resolving one of the issues preventing the U.S. from achieving Party status under these international agreements.

Conclusion

Taking steps such as those suggested above would help to address some of the issues and conflicts embedded in the current bills and increase the workability of the bills as proposed. At the same time, Congress needs to ensure that EPA receives adequate resources to do all that would be required for a successful launch while ensuring that EPA can develop an adequate infrastructure to meet all that the bills would require. If this can be done, it would go a long way to ensuring the long-term success of TSCA modernization.

---

[14] The memorandum states that federal agencies regulating biotechnology products "should continually strive to improve predictability, increase efficiency, and reduce uncertainty in their regulatory processes and requirements." Improvements must:

- Maintain high standards that are based on the best available science and that deliver appropriate health and environmental protection;
- Establish transparent, coordinated, predictable, and efficient regulatory practices across agencies with overlapping jurisdiction; and
- Promote public confidence in the oversight of the products of biotechnology through clear and transparent public engagement.

The memorandum initiates a process to help advance these aims, beginning with the following one-year objectives: (1) development of an updated Coordinated Framework to clarify the roles and responsibilities of the agencies that regulate the products of biotechnology; (2) formulation of a long-term strategy to ensure that the federal regulatory system is equipped to assess efficiently the risks, if any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, promoting public confidence in the regulatory process, increasing transparency and predictability, and reducing unnecessary costs and burdens; and (3) commissioning an external, independent analysis of the future landscape of biotechnology products.

[15] Last year, the J. Craig Venter Institute issued a landmark analysis of the domestic biotechnology regulatory system in which it highlighted the critical need for modernizing the Coordinated Framework. J. Craig Venter Institute. *Synthetic Biology and the U.S. Biotechnology Regulatory System: Challenges and Options* (May 2014), available at http://www.jcvi.org/cms/fileadmin/site/research/projects/synthetic-biology-and-the-us-regulatory-system/full-report.pdf. More recently, the National Research Council of the National Academies issued on March 13, 2015, *Industrialization of Biology: A Roadmap to Accelerate the Advance Manufacturing of Chemicals*, available at http://www.nap.edu/catalog/19001/industrialization-of-biology-a-roadmap-to-accelerate-the-advanced-manufacturing. The report, prepared by the Board on Chemical Sciences and Technology, Board on Life Sciences, Division on Earth and Life Studies, identified the challenges and opportunities posed by the current regulatory system relating to biotechnology and synthetic biology.

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 7/10/2015 9:21:46 PM
To: Kaiser, Sven-Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac78d3704ba94edbbd0da970921271ff-SKAISER]
CC: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
Subject: Update on our discussions...
Attachments: EPA TA - Orion - (7-10-15) - redline w explanation comments - v.2.1.rtf; EPA TA - Orion - EJMDD discussion draft - (7-10-15) - v.3.1.doc

Sven, for your team.

Priority here is to respond to T.A. from Michal, as opposed to reviewing these documents and pointing out concerns.

Attached:

- Orion v.2.1 = The EPW reported bill plus all of the EPA T.A. we received (described in comment bubbles).
- Orion v.3.1 = underlying 2.1 with the current state of discussions with Sens. Durbin and Markey.

this version now includes:

1. Implementation date
2. Expedited Action for TSCA workplan chemicals
3. User Fees fix
4. Changes to Persistence and Bioaccumulation
5. "At the discretion" removed
6. cost-benefit clarification
7. low priority info stuff
8. CBI reporting

LEFT UNSETTLED:

- Co-enforcement penalty (adequate works for us)
- 18 a science (close – just running one more trap)
- 18 a compelling local (trying to find another word)
- Substantial evidence/low priority (no creative thoughts on our part)
- assuming articles unchanged unless we receive new information

Purpose: In the nature of a substitute.

S. 697

To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE INTENDED TO BE PROPOSED BY _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act".

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(c) of the Toxic Substances Control Act (15 U.S.C. 2601(c)) is amended—

(1) by striking "It is the intent" and inserting the following:

"(1) ADMINISTRATION.—It is the intent";

(2) in paragraph (1) (as so redesignated), by inserting ", as provided under this Act" before the period at the end; and

(3) by adding at the end the following:

"(2) REFORM.—This Act, including reforms in accordance with the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act—

"(A) shall be administered in a manner that—

"(i) protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and

"(ii) ensures that appropriate information on chemical substances and mixtures is available to public health officials and first responders in the event of an

emergency; and

"(B) shall not displace or supplant common law rights of action or remedies for civil relief.".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) by redesignating paragraphs (4), (5), (6), (7), (8), (9), (10), (11), (12), (13), and (14) as paragraphs (5), (6), (7), (8), (9), (10), (12), (13), (17), (18), and (19), respectively;

(2) by inserting after paragraph (3) the following:

"(4) CONDITIONS OF USE.—The term 'conditions of use' means the intended, known, or reasonably foreseeable circumstances the Administrator determines a chemical substance is manufactured, processed, distributed in commerce, used, or disposed of.";

(3) by inserting after paragraph (10) (as so redesignated) the following:

"(11) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.—The term 'potentially exposed or susceptible population' means 1 or more groups—

"(A) of individuals within the general population who may be—

"(i) differentially exposed to chemical substances under the conditions of use; or

"(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

"(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; and

(4) by inserting after paragraph (13) (as so redesignated) the following:

"(14) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.

"(15) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the conditions of use.

"(16) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of injury to health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of injury to—

"(A) the general population; or

"(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

The Toxic Substances Control Act is amended by inserting after section 3 (15 U.S.C. 2602) the following:

"SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

"(a) Definition of Guidance.—In this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.

"(b) Deadline.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.

"(c) Use of Science.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance on the use of science in making decisions under sections 4, 4A, 5, and 6.

"(2) GOAL.—A goal of the policies, procedures, and guidance described in paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) REQUIREMENTS.—The policies, procedures, and guidance issued under this section shall ~~describe the manner in which the Administrator shall ensure that —~~ **ensure that—**

Commented [S1]: To be consistent with language in other subsections and better clarify purpose of the policies, procedures, and guidance.

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;

"(B) to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate~~, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.~~ **existing relevant policies, procedures, and guidance, as appropriate and consistent with this Act.**

Commented [S2]: Per TA, to simplify and avoid needing to provide a comprehensive list of such documents.

"(e) Review.—Not later than 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(1) review the adequacy of any policies, procedures, and guidance developed under this section, including animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this Act; and

"(2) after providing public notice and an opportunity for comment, revise the policies, procedures, and guidance if necessary to reflect new scientific developments or understandings.

"(f) Sources of Information.—In carrying out sections 4, 4A, 5, and 6, the Administrator shall take into consideration information relating to a chemical substance, including hazard and exposure information, under the conditions of use that is reasonably available to the Administrator, including information that is—

"(1) submitted to the Administrator pursuant to any rule, consent agreement, order, or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act, by—

"(A) manufacturers or processors of a substance;

"(B) the public;

"(C) other Federal departments or agencies; or

"(D) the Governor of a State or a State agency with responsibility for protecting health or the environment;

"(2) submitted to a governmental entity in any jurisdiction pursuant to a governmental requirement relating to the protection of health or the environment; or

"(3) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible by the Administrator.

"(g) Testing of Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator shall establish policies ~~and~~**,** procedures**, and guidance** for the testing of chemical substances or mixtures under section 4.

"(2) GOAL.—A goal of the policies ~~and~~**,** procedures**, and guidance** established under paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) CONTENTS.—The policies ~~and~~**,** procedures**, and guidance** established under paragraph (1) shall—

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition

that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential; **and**

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations~~;~~**.**

~~"(C) require the Administrator to~~**"(4) EPIDEMIOLOGICAL STUDIES.—Before prescribing epidemiological studies of employees, the Administrator shall** consult with the Director of the National Institute for Occupational Safety and Health. ~~prior to prescribing epidemiologic studies of employees; and~~

~~"(D) require that prior to making a request or adopting a requirement for testing using vertebrate animals, the Administrator shall take into consideration, as appropriate and to the extent practicable, reasonably available—~~

Commented [S3]: Moved to section 4(c)(1)(A) to integrate with other vertebrate animal testing provisions.

~~"(i) toxicity information;~~

~~"(ii) computational toxicology and bioinformatics;~~

~~* 1 "(iii) high-throughput screening methods and the prediction models of those methods; and~~

~~* 2 "(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.~~

"(h) Safety Assessments and Safety Determinations.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(C) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall identify the substances subject to safety assessments and safety determinations to be completed that year.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(A) IN GENERAL.—The Administrator shall establish, by rule, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

"(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

"(C) MINIMUM ~~REQUIREMENTS.—AT A MINIMUM, THE~~ REQUIREMENTS.—**The** policies and procedures under this paragraph ~~shall—~~ **shall, at a minimum—**

"(i) describe—

"(I) the manner in which the Administrator will identify informational needs and seek that information from the public;

"(II) the information (including draft safety assessments) that may be submitted by interested individuals or entities, including States; and

"(III) the criteria by which ~~that~~ information **submitted by interested individuals or entities** will be evaluated;

"(ii) require ~~the Administrator—~~ **that each draft and final safety assessment and safety determination of the Administrator include a description of—**

~~"(I)(aa) to define~~**"(I)(aa)** the scope of the safety assessment and safety determination to be conducted under section 6, including the hazards, exposures, **and** conditions of use **of the chemical substance**, and potentially exposed and susceptible populations that the Administrator ~~expects to consider~~ **has considered** in a safety assessment; **and**

"(bb) ~~to explain~~ the basis for the scope of the safety assessment and safety determination;

~~and~~

~~"(cc) to accept comments regarding the scope of the safety assessment and safety determination; and~~

~~"(II)(aa) to identify the items described in subclause (I) that the Administrator has considered in the final safety assessment; and~~

~~"(bb) to explain the basis for the consideration of those items;~~

~~"(iii) describe~~**"(II)** the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the conditions of use ~~will be~~ **were** considered, and ~~explain~~ the basis for that consideration ~~in the final safety assessment;~~**;**

~~"(iv) require that each safety assessment and safety determination shall include—~~

~~"(I) a description of~~**"(III)** the weight of the scientific evidence of risk; and

~~"(II) a summary of~~**"(IV)** the information regarding the impact on health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies;

~~"(v)~~**"(iii)** establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination; and

~~"(vi)~~**"(iv)** when relevant information is provided or otherwise made available to the Administrator, ~~shall~~ **require the Administrator to** consider the extent of Federal regulation under other Federal laws.

Commented [S4]: Per TA, to clarify what information is being referred to.

Commented [S5]: Per TA, changes for clarity and apply requirements to both draft and final safety assessments and safety determinations.

"(D) GUIDANCE.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop guidance to assist interested persons in developing their own draft safety assessments and other information for submission to the Administrator, which may be considered at the discretion of the Administrator.

"(ii) REQUIREMENT.—The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing a draft safety assessment for consideration by the Administrator.

"(i) Publicly Available Information.—Subject to section 14, the Administrator shall—

"(1) make publicly available a nontechnical summary, and the final version, of each safety assessment and safety determination;

"(2) provide public notice and an opportunity for comment on each proposed safety assessment and safety determination; and

"(3) make public in a final safety assessment and safety determination—

"(A) the list of studies considered by the Administrator in carrying out the safety assessment or safety determination; and

"(B) the list of policies, procedures, and guidance that were followed in carrying out the safety assessment or safety determination.

"(j) Consultation With Science Advisory Committee on Chemicals.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish an advisory committee, to be known as the 'Science Advisory Committee on Chemicals' (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, on the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(5) RELATIONSHIP TO OTHER LAW.—All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).".

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is

Commented [S6]: Per TA, these changes replace the Interagency Testing Committee with a general authority for other agencies to request EPA to conduct testing under TSCA to meet their needs. That authority is provided under new paragraph (5) below.

amended—

(1) by striking subsections (a), (b), (c), (d), ~~and (g);~~**(e), and (g);**

~~(2) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively;~~

~~(3) in subsection (f) (as so redesignated)—~~

~~(A) by striking "rule" each place it appears and inserting "rule, testing consent agreement, or order";~~

~~(B) by striking "under subsection (a)" each place it appears and inserting "under this subsection"; and~~

~~(C) in paragraph (1)—~~

~~(i) in subparagraph (A)(v), by inserting ", without taking into account cost or other nonrisk factors" after "the environment"; and~~

~~(ii) in subparagraph (B), in the last sentence, by striking "rulemaking";~~

~~(4) in subsection (g) (as so redesignated)—~~**(2) in subsection (f)—**

(A) in the first sentence—

(i) by striking "from cancer, gene mutations, or birth defects"; and

(ii) by inserting ", without taking into account cost or other nonrisk factors" before the period at the end; and

(B) by striking the last sentence; and

~~(5)~~**(3)** by inserting before subsection (f) ~~(as so redesignated)~~ the following:

"(a) Development of New Information on Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section if the Administrator determines that the information is necessary—

"(A) to review a notice under section 5(d) or to perform a safety assessment or safety determination under section 6;

"(B) to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4) or under a rule promulgated under section 6(d)(3);

"(C) pursuant to section 12(a)(4); or

"(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

"(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.

"(B) PROHIBITION.—Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.

"(C) LIMITATION.—The Administrator may require the development of new

information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

"(3) FORM.—The Administrator may require the development of information described in paragraph (1) or (2) by—

"(A) promulgating a rule;

"(B) entering into a testing consent agreement; or

"(C) issuing an order.

"(4) CONTENTS.—

"(A) IN GENERAL.—A rule, testing consent agreement, or order issued under this subsection shall include—

"(i) identification of the chemical substance or mixture for which testing is required;

"(ii) identification of the persons required to conduct the testing;

"(iii) test protocols and methodologies for the development of information for the chemical substance or mixture, including specific reference to any reliable nonanimal test procedures; and

"(iv) specification of the period within which individuals and entities required to conduct the testing shall submit to the Administrator the information developed in accordance with the procedures described in clause (iii).

"(B) CONSIDERATIONS.—In determining the procedures and period to be required under subparagraph (A), the Administrator shall take into consideration—

"(i) the relative costs of the various test protocols and methodologies that may be required; and

"(ii) the reasonably foreseeable availability of facilities and personnel required to perform the testing.

"(5) CONSIDERATION OF FEDERAL AGENCY RECOMMENDATIONS.—The Administrator shall consider the recommendations of other Federal agencies regarding the chemical substances and mixtures to which the Administrator shall give priority consideration under this section.

"(b) Statement of Need.—

"(1) IN GENERAL.—In promulgating a rule, entering into a testing consent agreement, or issuing an order for the development of additional information (including information on exposure or exposure potential) pursuant to this section, the Administrator shall—

"(A) identify the need intended to be met by the rule, agreement, or order;

"(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of vertebrate animals.

"(2) EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an order is warranted instead of promulgating a rule or entering into a testing consent agreement.

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a description of—

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

"(ii) the extent to which the Administrator has obtained or attempted to obtain the information through voluntary submissions; and

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) ~~encouraging and facilitating—~~ **prior to making a request or adopting a requirement for testing using vertebrate animals, taking into consideration, as appropriate and to the extent practicable, reasonably available—**

Commented [S7]: Moved here from section 3A(g) to integrate with other vertebrate animal testing provisions.

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

** **1** "(iii) high-throughput screening methods and the prediction models of those methods; and

** **2** "(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.**;**

"(B) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

"(I) animal-based studies; and

"(II) emerging methods and models; and

~~"(B)~~**"(C)** funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information under this title that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

"(C) identify in the strategic plan developed under subparagraph (A) particular alternative test methods or testing strategies that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information of equivalent scientific reliability and quality to that which would be obtained from vertebrate animal testing;

"(D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific reliability, relevance, and equivalent information and the test methods and strategies identified in subparagraph (C);

"(E) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation;

"(F) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing under this title; and

"(G) identify synergies with the related information requirements of other jurisdictions to minimize the potential for additional or duplicative testing.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

"(A) there is sufficient evidence from several independent sources of information to

support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(4) VOLUNTARY TESTING.—

"(A) IN GENERAL.—Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative or nonanimal test method or testing strategy that the Administrator has determined under paragraph (2)(C) to be scientifically reliable, relevant, and capable of providing equivalent information, before conducting new animal testing.

"(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph—

"(i) requires the Administrator to review the basis on which the person is conducting testing described in subparagraph (A);

"(ii) prohibits the use of other test methods or testing strategies by any person for purposes other than developing information for submission under this title on a voluntary basis; or

"(iii) prohibits the use of other test methods or testing strategies by any person, subsequent to the attempt to develop information using the test methods and testing strategies identified by the Administrator under paragraph (2)(C).

"(d) Testing Requirements.—

Commented [S8]: Per TA, changes in this subsection are made to better track current TSCA and clarify the parties eligible for exemptions and the duration of the reimbursement period.

"(1) IN GENERAL.—The Administrator may require the development of information by—

"(A) manufacturers and processors of the chemical substance or mixture; and

"(B) ~~subject to paragraph (3),~~ persons that begin to manufacture or process the chemical substance or **mixture** ~~mixture—~~

~~"(i)~~ after the effective date of the rule, testing consent agreement, or order.~~; but~~

~~"(ii) before the period ending on the later of—~~

~~"(I) 5 years after the date referred to in clause (i); or~~

~~* 3 "(II) the last day of the period that begins on the date referred to in clause (i) and that is equal to the period that the Administrator determines was necessary to develop the~~

~~information.~~

"(2) DESIGNATION.—The Administrator may permit 2 or more persons identified in subparagraph (A) or (B) of paragraph (1) to designate 1 of the persons or a qualified third party—

"(A) to develop the information; and

"(B) to submit the information on behalf of the persons making the designation.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—A person otherwise subject to a rule, testing consent agreement, or order under this section may submit to the Administrator an application for an exemption on the basis that ~~the information~~ **submission of information by the applicant on the chemical substance or mixture would be duplicative of—**

"(i) information on the chemical substance or mixture that—

"(I) has been submitted to the Administrator pursuant to a rule, consent agreement, or order under this section; or

"(II) is being developed by a person designated under paragraph (2); or

"(ii) information on an equivalent chemical substance or mixture that—

"(I) has been submitted to the Administrator pursuant to a rule, consent agreement, or order under this section; or

"(II) is being developed by a person designated under paragraph (2).

"(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

"(i) IN GENERAL.—If the Administrator accepts an application submitted under subparagraph (A), **before the end of the reimbursement period described in clause (iii),** the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as agreed to between the applicant and the designee.

"(ii) ARBITRATION.—If the applicant and a person designated under paragraph (2) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.

"(iii) REIMBURSEMENT PERIOD.—For the purposes of this subparagraph, the reimbursement period for any information for a chemical substance or mixture is a period—

"(I) beginning on the date the information is submitted in accordance with a rule, testing consent agreement, or order under this section; and

"(II) ending on the later of—

"(aa) 5 years after the date referred to in subclause (I); or

** **3** "~~(II)~~**"(bb)** the last day of the period that begins on the date referred to in ~~clause (i)~~ **subclause (I)** and that is equal to the period that

the Administrator determines was necessary to develop the information.

"(C) TERMINATION.—If, after granting an exemption under this paragraph, the Administrator determines that no person designated under paragraph (2) has complied with the rule, testing consent agreement, or order, the Administrator shall—

"(i) by order, terminate the exemption; and

"(ii) notify in writing each person that received an exemption of the requirements with respect to which the exemption was granted.

"(4) TIERED TESTING.—

"(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.

"(B) SCREENING-LEVEL TESTS.—

"(i) IN GENERAL.—The screening-level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.

"(ii) USE.—Screening-level tests shall be used—

"(I) to screen chemical substances or mixtures for potential adverse effects; and

"(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.

"(C) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for safety assessments or safety determinations, the Administrator may require more advanced tests for potential health or environmental effects or exposure potential.

"(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

"(e) Transparency.—Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders and all information submitted under this section.".

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the third sentence by ~~striking "section 4(e)" and inserting "section 4(f)".~~ **inserting "(as in effect on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act)" after "Toxic Substances Control Act".**

SEC. 6. PRIORITIZATION SCREENING.

The Toxic Substances Control Act is amended by inserting after section 4 (15 U.S.C. 2603) the following:

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) Prioritization Screening Process and List of Substances.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish, by rule, a risk-based screening process and ~~explicit~~ criteria for identifying existing chemical substances that are—

Commented [S9]: Per TA, so as not to imply that other criteria specified in the bill are not to be explicit.

"(A) a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances'); and

"(B) a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').

"(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(A) IN GENERAL.—Before the date of promulgation of the rule under paragraph (1) and not later than 180 days after the date of enactment of this section, the **Administrator shall** ~~Administrator—~~

~~"(i) shall take into consideration and~~ publish an initial list of high-priority substances and low-priority substances~~; and~~

~~"(ii) pursuant to section 6(b), may initiate or continue safety assessments and safety determinations for those high-priority substances~~.

Commented [S10]: Per TA, to simplify language and avoid unnecessary redundancy with section 6(b).

"(B) REQUIREMENTS.—

"(i) IN GENERAL.—The initial list of chemical substances shall contain at least 10 high-priority substances, at least 5 of which are drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, and at least 10 low-priority substances.

"(ii) SUBSEQUENTLY IDENTIFIED SUBSTANCES.—Insofar as possible, at least 50 percent of all substances subsequently identified by the Administrator as high-priority substances shall be drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, until all Work Plan chemicals have been designated under this subsection.

"(iii) PERSISTENCE AND BIOACCUMULATION.—In developing the initial list and in identifying additional high-priority substances, the Administrator shall give preference to chemical substances scored as high for persistence and bioaccumulation in the October 2014 TSCA Work Plan and subsequent updates.

"(C) ADDITIONAL CHEMICAL REVIEWS.—The Administrator shall, as soon as practicable and not later than—

"(i) 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 20 high-priority substances have undergone or are

undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 20 low-priority substances have been designated; and

"(ii) 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 25 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 25 low-priority substances have been designated.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In ~~carrying out~~ **implementing the prioritization screening process established under** paragraph (1), the Administrator shall take into consideration active substances, as determined under section 8, which may include chemical substances on the interim list of active substances established under that section.

Commented [S11]: Per TA, for clarity, here and in next clause.

"(ii) INACTIVE SUBSTANCES.—In ~~carrying out~~ **implementing the prioritization screening process established under** paragraph (1), the Administrator may take into consideration inactive substances, as determined under section 8, that the Administrator determines—

"(I)(aa) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) have the potential for high hazard and widespread exposure; or

"(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) with respect to which there exists the potential for residual high hazards or widespread exposures not otherwise addressed by the regulatory or other action.

"(iii) REPOPULATION.—

"(I) IN GENERAL.—On the completion of a safety determination under section 6 for a chemical substance, the Administrator shall remove the chemical substance from the list of high-priority substances established under this subsection.

"(II) ADDITIONS.—The Administrator shall add at least 1 chemical substance to the list of high-priority substances for each chemical substance removed from the list of high-priority substances established under this subsection, until a safety assessment and safety determination is completed for all **chemical substances not designated as high-priority.** ~~high-priority substances.~~

Commented [S12]: Per TA, to clarify that all substances other than low-priority substances are to undergo safety assessments and safety determinations, once designated high-priority substances

~~"(III) Low-priority substances.—If a low-priority substance is subsequently designated as a high-priority substance, the Administrator shall~~

Commented [S13]: Per TA, not needed; redundant.

~~remove that substance from the list of low-priority substances.~~

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) except as provided under paragraph (2), not later than 180 days after the effective date of the final rule under paragraph (1), begin the prioritization screening process; and

"(II) make every effort to complete the designation of all active substances as high-priority substances or low-priority substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical substance as a high-priority substance or low-priority substance.

"(iii) CONSIDERATION.—

"(I) IN GENERAL.—The Administrator shall screen substances and designate high-priority substances taking into consideration the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in a timely manner.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.

"(C) SCREENING OF CATEGORIES OF SUBSTANCES.—The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate designations of high-priority substances and low-priority substances and safety assessments and safety determinations for high-priority substances.

"(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—The Administrator shall keep current and publish a list of chemical substances ~~that —~~ **that includes and identifies substances—**

~~"(i)~~ **"(i) that** are being considered in the prioritization screening process and the status of the ~~chemical~~ substances in the prioritization process~~, including those chemical substances~~**;**

"(ii) for which prioritization decisions have been ~~deferred; and~~ **postponed pursuant to subsection (b)(5), including the basis for the postponement; and**

~~"(ii)~~ **"(iii) that** are designated as high-priority substances or low-priority substances, including the bases for such designations.

"(4) CRITERIA.—The criteria described in paragraph (1) shall account for—

"(A) the recommendation of the Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances appropriate for prioritization screening;

Commented [S14]: Per TA, to clarify that all three types of substances are to be included on the list, that prioritization decisions on substances lacking sufficient information are postponed for a finite period and not deferred indefinitely, and that the bases for postponements are to be made available.

"(B) the hazard and exposure potential of the chemical substance (or category of substances), including persistence, bioaccumulation, and specific scientific classifications and designations by authoritative governmental entities;

"(C) the conditions of use or significant changes in the conditions of use of the chemical substance;

"(D) evidence and indicators of exposure potential to humans or the environment from the chemical substance, including potentially exposed or susceptible populations;

"(E) the volume of a chemical substance manufactured or processed;

"(F) whether the volume of a chemical substance as reported ~~under~~ **pursuant to** a rule promulgated pursuant to section 8(a) has significantly increased or decreased ~~during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance~~;

Commented [S15]: Per TA, to avoid ambiguity and unnecessary complication in specifying how EPA is to determine whether a volume has significantly changed.

"(G) the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

"(H) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a high-priority or a low-priority substance.

"(b) Prioritization Screening Process and Decisions.—

"(1) IN ~~GENERAL.—THE~~ GENERAL.—**In implementing the** prioritization screening process developed under subsection (a) ~~shall include a requirement that~~, the Administrator shall—

Commented [S16]: Per TA, for clarity in direction being provided to EPA.

"(A) identify the chemical substances being considered for prioritization;

"(B) request interested persons to supply information regarding the chemical substances being considered;

"(C) apply the criteria identified in subsection (a)(4); and

"(D) subject to paragraph (5) and using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.

"(2) ~~INTEGRATION OF~~ **REASONABLY AVAILABLE** INFORMATION.—The prioritization screening decision regarding a chemical substance shall ~~integrate~~ **consider** any hazard and exposure information relating to the chemical substance that is **reasonably** available to the Administrator.

Commented [S17]: Per TA, changes to clarify information to be used by EPA.

"(3) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(A) shall identify as a high-priority substance a chemical substance that, relative to other active chemical substances, the Administrator determines has the potential for

significant hazard and significant exposure;

"(B) may identify as a high-priority substance a chemical substance that, relative to other active chemical substances, the Administrator determines has the potential for significant hazard or significant exposure; and

"(C) may identify as a high-priority substance an inactive substance, as determined under subsection (a)(3)(A)(ii) and section 8(b), that the Administrator determines warrants a safety assessment and safety determination under section 6.

"(4) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that the chemical substance is likely to meet the safety standard.

"(5) ~~DEFERRING~~ **POSTPONING** A DECISION.—If the Administrator determines that additional information is ~~required~~ **needed** to establish the priority of a chemical substance under this section, the Administrator may ~~defer~~ **the postpone a** prioritization screening decision for a reasonable period—

Commented [S18]: Per TA, for clarity that such decisions are postponed for a finite period and not deferred indefinitely.

"(A) to allow for the submission of additional information by an interested person and for the Administrator to evaluate the additional information; or

"(B) to require the development of information pursuant to a rule, testing consent agreement, or order issued under section 4(a)(2).

"(6) DEADLINES FOR SUBMISSION OF INFORMATION.—If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of the information.

"(7) NOTICE AND COMMENT.—The Administrator shall—

"(A) publish, including in the Federal Register, the proposed decisions made under paragraphs (3), (4), and (5) and the basis for the decisions;

~~and~~**"(B) identify the information and analysis on which the documents are based; and**

~~"(B)~~ **"(C)** provide 90 days for public comment.

"(8) REVISIONS OF PRIOR DESIGNATIONS.—

"(A) IN GENERAL.—At any time, and at the discretion of the Administrator, the Administrator may revise the designation of a chemical substance as a high-priority substance or a low-priority substance based on information available to the Administrator after the date of the determination under paragraph (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.

"(9) OTHER INFORMATION RELEVANT TO PRIORITIZATION.—

"(A) IN GENERAL.—If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State proposes an administrative action or

enacts a statute or takes an administrative action to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not designated as a high-priority substance, the Governor or State agency with responsibility for implementing the statute or administrative action shall notify the Administrator.

"(B) REQUESTS FOR INFORMATION.—Following receipt of a notification provided under subparagraph (A), the Administrator may request any available information from the Governor or the State agency with respect to—

"(i) scientific evidence related to the hazards, exposures and risks of the chemical substance under the conditions of use which the statute or administrative action is intended to address;

"(ii) any State or local conditions which warranted the statute or administrative action;

"(iii) the statutory or administrative authority on which the action is based; and

"(iv) any other available information relevant to the prohibition or other restriction, including information on any alternatives considered and their hazards, exposures, and risks.

"(C) PRIORITIZATION SCREENING.—The Administrator shall conduct a prioritization screening under this subsection for all substances that—

"(i) are the subject of notifications received under subparagraph (A); and

"(ii) the Administrator determines—

"(I) are likely to have significant health or environmental impacts;

"(II) are likely to have significant impact on interstate commerce; or

"(III) have been subject to a prohibition or other restriction under a statute or administrative action in 2 or more States.

"(D) AVAILABILITY TO PUBLIC.—Subject to section 14 and any applicable State law regarding the protection of confidential information provided to the State or to the Administrator, the Administrator shall make information received from a Governor or State agency under subparagraph (A) publicly available.

"(E) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall preempt a State statute or administrative action, require approval of a State statute or administrative action, or apply section 15 to a State.

"(10) REVIEW.—Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Administrator shall—

"(A) review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and

"(B) if necessary, modify the prioritization screening process.

"(11) EFFECT.—Subject to section 18, a designation by the Administrator under this

section with respect to a chemical substance shall not affect—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance; or

"(B) the regulation of those activities.

"(c) Additional Priorities for Safety Assessments and Determinations.—

"(1) REQUIREMENTS.—

"(A) IN GENERAL.—The ~~prioritization screening process developed~~ **rule promulgated** under subsection (a) shall—

"(i) include a process by which a manufacturer or processor of an active chemical substance that has not been designated a high-priority substance or is not in the process of a prioritization screening by the Administrator, may request that the Administrator designate the substance as an additional priority for a safety assessment and safety determination, subject to the payment of fees pursuant to section ~~26(b)(3)(E)~~ **26(b)(3)(D)**;

"(ii) specify the information to be provided in such requests; and

"(iii) specify the criteria **(which may include criteria identified in subsection (a)(4)) that** the Administrator shall use to determine whether or not to grant such a request, which shall include whether the substance is subject to restrictions imposed by statutes enacted or administrative actions taken by 1 or more States on the manufacture, processing, distribution in commerce, or use of the substance.

"(B) PREFERENCE.—Subject to paragraph (2), in deciding whether to grant requests under this subsection the Administrator shall give a preference to requests concerning substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

"(C) EXCEPTIONS.—Chemical substances for which requests have been granted under this subsection shall not be subject to subsection (a)(3)(A)(iii) or section 18(b).

"(2) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

"(A) ~~if a sufficient number of additional priority requests meet the requirements of paragraph (1),~~ **the number of substances designated to undergo safety assessments and safety determinations under the process and criteria pursuant to paragraph (1) is** not less than 25 percent, or more than 30 percent, of the cumulative number of substances designated to undergo safety assessments and safety determinations under subsections (a)(2) and (b)(3) ~~are substances designated under the process and criteria pursuant to paragraph (1);~~**(except that if less than 25 percent are received by the Administrator, the Administrator shall grant each request that meets the requirements of paragraph (1));**

"(B) the resources allocated to conducting safety assessments and safety determinations for additional priorities designated under this subsection are proportionate to the number of such substances relative to the total number of

Commented [S19]: Per TA, to clarify it is the rule that is to include the process in (i), which is a process different from and in addition to the prioritization screening process.

Commented [S20]: Correcting cross-reference based on later relettering of subparagraphs in section 26(b)(3).

Commented [S21]: To clarify that criteria used to prioritize chemicals can also be used here at EPA discretion.

Commented [S22]: Per TA, for clarity as to how percentages are to be calculated.

substances **currently** designated to undergo safety assessments and safety determinations under this section; and

"(C) the number of additional priority requests stipulated under subparagraph (A) is in addition to the total number of high-priority substances identified under subsections (a)(2) and (b)(3).

"(3) ADDITIONAL REVIEW OF WORK PLAN CHEMICALS FOR SAFETY ASSESSMENT AND SAFETY DETERMINATION.—In the case of a request under paragraph (1) with respect to a chemical substance identified by the Administrator in the October 2014 Work Plan—

"(A) the 30-percent cap specified in paragraph (2)(A) shall not apply and the addition of Work Plan chemicals shall be at the discretion of the Administrator; and

"(B) notwithstanding paragraph (1)(C), requests for additional Work Plan chemicals under this subsection shall be considered high-priority chemicals subject to section 18(b) but not subsection (a)(3)(A)(iii).

"(4) REQUIREMENTS.—

"(A) IN GENERAL.—The public shall be provided notice and an opportunity to comment on requests submitted under this subsection.

"(B) DECISION BY ADMINISTRATOR.—Not later than 180 days after the date on which the Administrator receives a request under this subsection, the Administrator shall decide whether or not to grant the request.

"(C) ASSESSMENT AND DETERMINATION.—If the Administrator grants a request under this subsection, the safety assessment and safety determination—

"(i) shall be conducted in accordance with the deadlines and other requirements of sections 3A(i) and 6; and

"(ii) shall not be expedited or otherwise subject to special treatment relative to high-priority substances designated pursuant to subsection (b)(3) that are undergoing safety assessments and safety determinations.".

SEC. 7. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.";

(2) by striking subsection (b);

(3) by redesignating subsection (a) as subsection (b);

(4) by redesignating subsection (i) as subsection (a) and moving the subsection so as to appear at the beginning of the section;

(5) in subsection (b) (as so redesignated)—

Commented [S23]: Per TA, to clarify that this subparagraph relates to the allocation of resources among chemicals in the pipeline at any given time.

(A) in the subsection heading, by striking "In General" and inserting "Notices";

(B) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking "subsection (h)" and inserting "paragraph (3) and subsection (h)"; and

(ii) in the matter following subparagraph (B)—

(I) by striking "subsection (d)" and inserting "subsection (c)"; and

(II) by striking "and such person complies with any applicable requirement of subsection (b)"; and

(C) by adding at the end the following:

"(3) ARTICLE CONSIDERATION.—The Administrator may require ~~the~~ notification **under this section** for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification.";

Commented [S24]: To clarify the reference to notification is to a section 5 notice, not a section 13 import notification.

(6) by redesignating subsections (c) and (d) as subsections (d) and (c), respectively, and moving subsection (c) (as so redesigned) so as appear after subsection (b) (as redesignated by paragraph (3));

(7) in subsection (c) (as so redesignated)—

(A) by striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—The notice required by subsection (b) shall include, with respect to a chemical substance—

"(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

"(B) **all known or reasonably ascertainable** information regarding conditions of use and reasonably anticipated exposures.";

Commented [S25]: Per TA, to mirror current TSCA's language.

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A)—

(I) by striking "subsection (a)" and inserting "subsection (b)"; and

(II) by striking "or of data under subsection (b)";

(ii) in subparagraph (A), by adding "and" after the semicolon at the end;

(iii) in subparagraph (B), by striking "; and" and inserting a period; and

(iv) by striking subparagraph (C); and

(C) in paragraph (3), by striking "subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "subsection (b) and for which the notification period prescribed by subsection (b) or (d)";

(8) by striking subsection (d) (as redesignated by paragraph (6)) and inserting the

following:

"(d) Review of Notice.—

"(1) INITIAL REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall—

"(i) conduct an initial review of the notice;

"(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

"(iii) make ~~any necessary~~ **a** determination under paragraph (3).

Commented [S26]: Per TA, to be clear that a determination is necessary in each case.

"(B) EXTENSION.—Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.

"(2) INFORMATION SOURCES.—In evaluating a notice under paragraph (1), the Administrator shall take into consideration—

"(A) any relevant information identified in subsection (c)(1); and

"(B) any other relevant additional information available to the Administrator.

"(3) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), based on the information described in paragraph (2), and subject to section 18(g), the Administrator shall determine that—

"(A) the relevant chemical substance or significant new use is not likely to meet the safety standard, in which case the Administrator shall take appropriate action under paragraph (4);

"(B) the relevant chemical substance or significant new use is likely to meet the safety standard, in which case the Administrator shall allow the review period to expire without additional restrictions; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraphs (4) and (5).

"(4) RESTRICTIONS.—

"(A) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—If the Administrator makes a determination under subparagraph (A) or (C) of paragraph (3) with respect to a notice submitted under subsection (b)—

"(I) the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, as appropriate, shall prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the restrictions specified in the consent agreement or order that the

Administrator determines are sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard; and

"(II) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, except in compliance with the restrictions specified in the consent agreement or order.

"(ii) LIKELY TO MEET STANDARD.—If the Administrator makes a determination under subparagraph (B) of paragraph (3) with respect to a chemical substance or significant new use for which a notice was submitted under subsection (b), at the end of the applicable period for review under paragraph (1), the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use.

"(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall—

"(i) ~~take into consideration~~ **consider** whether to promulgate a rule pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance~~, or of the chemical substance for a new use, that is not in compliance with~~ **that does not conform to** the restrictions imposed by the consent agreement or order; and

Commented [S27]: Per TA, identifying a significant new use is already specified in opening phrase and is not needed here.

Commented [S28]: Per TA, consistent with current basis for SNURs under TSCA.

"(ii)(I) initiate a rulemaking described in clause (i); or

"(II) publish a statement describing the reasons of the Administrator for not initiating a rulemaking.

"(C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include, as appropriate—

"(i) subject to section 18(g), a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator

"(ii) a requirement that manufacturers or processors of the chemical substance shall—

"(I) make and retain records of the processes used to manufacture or process, as applicable, the chemical substance; or

"(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, use, or disposal, as applicable, of the chemical substance, subject to section 4;

"(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

"(I) in general; or

"(II) for a particular use;

"(iv) a prohibition or other restriction of—

"(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

"(II) any method of commercial use of the chemical substance; or

"(III) any method of disposal of the chemical substance; or

"(v) a prohibition or other restriction on the manufacture, processing, or distribution in commerce of the chemical substance—

"(I) in general; or

"(II) for a particular use.

"(D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines ranks high for persistence and bioaccumulation, the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance is likely to meet the safety standard, reduce potential exposure to the substance to the maximum extent practicable.

"(E) WORKPLACE ~~EXPOSURES.—THE~~ EXPOSURES.—**To the extent practicable, the** Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

Commented [S29]: Per TA, to provide flexibility to do this where compatible with length of review period.

"(F) DEFINITION OF REQUIREMENT.—For purposes of this Act, the term 'requirement' as used in this section does not displace common law.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

"(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(C) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

"(D) on receipt of information the Administrator finds supports the determination under paragraph (3), shall promptly make the determination.";

(9) by striking subsections (e) through (g) and inserting the following:

"(e) Notice of Commencement.—

"(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer that has

submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—

"(A) the name of the manufacturer; and

"(B) the initial date of nonexempt commercial manufacture.

"(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

"(f) Further Evaluation.—The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—

"(1) a notice of commencement for a chemical substance under subsection (e); or

"(2) new information regarding the chemical substance.

"(g) Transparency.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, consent agreements, rules, and orders ~~of~~ **submitted under this section or made by** the Administrator **under this section**; and

Commented [S30]: Per TA, to clarify this applies both to information submitted to EPA and decisions made by EPA.

"(2) all information submitted or issued under this section."; and

(10) in subsection (h)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking "(a) or"; and

(ii) in subparagraph (A), by inserting ", without taking into account cost or other nonrisk factors" after "the environment";

(B) by striking paragraph (2);

(C) by redesignating paragraphs (3) through (6) as paragraphs (2) through (5), respectively;

(D) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking "subsections (a) and (b)" and inserting "subsection (b)";

(E) in paragraph (3) (as so redesignated)—

(i) in the first sentence, by striking "will not present an unreasonable risk of injury to health or the environment" and inserting "will meet the safety standard"; and

(ii) by striking the second sentence;

(F) in paragraph (4) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (b)"; and

(G) in paragraph (5) (as so redesignated), in the first sentence, by striking "paragraph (1) or (5)" and inserting "paragraph (1) or (4)".

SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections (g) and (h), respectively;

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) shall, as soon as practicable and not later than 6 months after the date on which a chemical substance is designated as a high-priority substance, define and publish the scope of the safety assessment and safety determination to be conducted pursuant to this section, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that the Administrator expects to consider;

"(3) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(4) shall complete **and publish** a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

Commented [S31]: To conform with language elsewhere that ties certain actions to publication of the safety assessment and determination.

"(5) shall promulgate ~~a~~ **any necessary** final rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; and

Commented [S32]: Per TA, to avoid implication that a rule is always to be required.

"(6) may extend any deadline under paragraph (4) or (5) for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under this subsection, plus any deferral under subsection (c)(2), does not exceed 2 years.

"(b) Prior Actions and Notice of Existing Information.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination ~~that was initiated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st~~ Century Act, prior to the effective date of the policies and, procedures, **and guidance** required to be established by the Administrator under section 3A or 4A.

Commented [S33]: Per TA, to clarify that an assessment or determination need not have been initiated before enactment, just before the new policies, procedures and guidance are in place.

"(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing

safety assessments and safety determinations.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or rule solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure.

"(3) NOTICE OF EXISTING INFORMATION.—

"(A) IN GENERAL.—The Administrator shall, where such information is available, take notice of existing information regarding hazard and exposure published by other Federal agencies and the National Academies and incorporate the information in safety assessments and safety determinations with the objective of increasing the efficiency of the safety assessments and safety determinations.

"(B) INCLUSION OF INFORMATION.—Existing information described in subparagraph (A) should be included to the extent practicable and where the Administrator determines the information is relevant and scientifically reliable.

"(c) Safety Determinations.—

"(1) IN GENERAL.—Based on a review of the information available to the Administrator, including draft safety assessments submitted by interested persons **pursuant to section 3A(h)(2)(D)**, and subject to section 18**(g)**, the Administrator shall ~~determine that—~~ **determine—**

~~"(A)~~ **"(A) by order, that** the relevant chemical substance meets the safety standard;

"(B) **that** the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by rule under subsection (d)—

"(i) impose restrictions necessary to ensure that the chemical substance meets the safety standard under the conditions of use; or

"(ii) if the safety standard cannot be met with the application of **other** restrictions **under subsection (d)(3)**, ban or phase out the chemical substance, as appropriate; or

"(C) **that** additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is necessary to make a safety assessment or safety determination for a high-priority substance, the Administrator—

"(A) shall provide an opportunity for interested persons to submit the additional information;

"(B) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

"(C) may defer, for a reasonable period consistent with the deadlines described in

Commented [S34]: Per TA, to clarify that such draft assessments are subject to the guidance developed by EPA applicable to such submissions.

Commented [S35]: Specifies the cross-reference is to the savings clauses of section 18.

Commented [S36]: Per TA, specifies such determinations are to be made by order, which, coupled with changes made below to section 19 of TSCA, ensure these determinations are subject to judicial review under that section.

Commented [S37]: To clarify the other restrictions available to EPA in such a case.

subsection (a), a safety assessment and safety determination until after receipt of the information; and

"(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety determination, shall make a determination under paragraph (1).

"(3) ESTABLISHMENT OF DEADLINE.—In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.

"(d) Rule.—

"(1) IMPLEMENTATION.—If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a rule establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

"(2) SCOPE.—

"(A) IN GENERAL.—The rule promulgated pursuant to this subsection—

"(i) may apply to mixtures containing the chemical substance, as appropriate;

"(ii) shall include dates by which compliance is mandatory, which—

"(I) shall be as soon as practicable;

"(II) in the case of a ban or phase-out of the chemical substance, shall implement the ban or phase-out in as short a period as practicable; and

"(III) as determined by the Administrator, may vary for different affected persons; and

"(iii) shall exempt replacement parts that are manufactured prior to the effective date of the rule for articles that are first manufactured prior to the effective date of the rule unless the Administrator finds the replacement parts contribute significantly to the identified risk; and

"(iv) shall, in selecting among prohibitions and other restrictions, apply such prohibitions or other restrictions to articles containing the chemical substance only to the extent necessary to address the identified risks in order to determine that the chemical substance meets the safety standard.

"(B) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines ranks high for persistence and bioaccumulation, the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance meets the safety standard, reduce exposure to the substance to the maximum extent practicable.

"(C) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(D) DEFINITION OF REQUIREMENT.—For the purposes of this Act, the term 'requirement' as used in this section does not displace common law.

"(3) RESTRICTIONS.—A restriction under paragraph (1) may include, as appropriate—

"(A) subject to section 18, a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator;

"(B) a requirement that manufacturers or processors of the chemical substance shall—

"(i) make and retain records of the processes used to manufacture or process the chemical substance;

"(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or

"(iii) monitor or conduct tests that are reasonably necessary to ensure compliance with the requirements of any rule under this subsection;

"(C) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

"(D) a requirement to ban or phase out, or ~~any other rule regarding,~~ **otherwise restrict** the manufacture, processing, or distribution in commerce of the chemical substance for—

Commented [S38]: To conform language with usage throughout the rest of the bill.

"(i) a particular use;

"(ii) a particular use at a concentration in excess of a level specified by the Administrator; or

"(iii) all uses;

"(E) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—

"(i) a particular use; or

"(ii) a particular use at a concentration in excess of a level specified by the Administrator;

"(F) a requirement to ban, phase out, or otherwise restrict any method of commercial use of the chemical substance;

"(G) a requirement to ban, phase out, or otherwise restrict any method of disposal of the chemical substance or any article containing the chemical substance; and

"(H) a requirement directing manufacturers or processors of the chemical substance to give notice of the Administrator's determination under subsection (c)(1)(B) to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph

(3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

"(5) EXEMPTIONS.—

"(A) IN GENERAL.—The Administrator may ~~exempt 1 or more uses of a chemical substance from any restriction in~~**, as part of** a rule promulgated under paragraph (1) **or in a separate rule, exempt 1 or more uses of a chemical substance from any restriction in a rule promulgated under paragraph (1)** if the Administrator determines that—

"(i) the ~~rule~~ **restriction** cannot be complied with, without—

"(I) harming national security;

"(II) causing significant disruption in the national economy due to the lack of availability of a chemical substance; or

"(III) interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or

"(ii) the use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

"(B) EXEMPTION ANALYSIS.—In proposing a rule under ~~paragraph (1) that includes an exemption under~~ this paragraph, the Administrator shall make publicly available any analysis conducted under this paragraph to assess the need for the exemption.

"(C) STATEMENT REQUIRED.—In making final a rule under ~~paragraph (1) that includes an exemption under~~ this paragraph, the Administrator shall include a statement describing how the analysis considered under subparagraph (B) was taken into account.

"(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—In determining whether an exemption should be granted under this paragraph for a chemical substance for which a ban or phase-out is **included in a** proposed **or final rule under paragraph (1)**, the Administrator shall take into consideration, to the extent practicable based on

Commented [S39]: Per TA, this and numerous conforming changes in this paragraph are needed to:
(1) clarify that exemptions, which must be granted via rules, may not always be included in the original risk management rule and may need to be provided later through a separate rule; and
(2) distinguish clearly between the two types of rules under this section: risk management rules issued under paragraph (1) [which may include exemptions, and subsequent exemption rules issued under paragraph (5).

reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more ~~technically and economically feasible~~ alternatives to the chemical substance **the Administrator determines to be technically and economically feasible and** most likely to be used in place of the chemical substance under the conditions of use ~~if the rule is promulgated~~.

Commented [S40]: To clarify that EPA is to make the determination of technical and economic feasibility.

"(E) CONDITIONS.—As part of a rule promulgated under **this** paragraph~~(1)~~, the Administrator shall include conditions ~~in any exemption established under this paragraph~~, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption.

"(F) DURATION.—

"(i) IN GENERAL.—The Administrator shall establish, as part of a rule under ~~paragraph (1) that contains an exemption under~~ this paragraph, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis.

"(ii) AUTHORITY OF ADMINISTRATOR.—The Administrator, by rule, may extend, modify, or eliminate ~~the~~ **an** exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or is no longer necessary.

"(iii) CONSIDERATIONS.—

"(I) IN GENERAL.—Subject to subclause (II), the Administrator shall issue exemptions and establish time periods by considering factors determined by the Administrator to be relevant to the goals of fostering innovation and the development of alternatives that meet the safety standard.

"(II) LIMITATION.—Any renewal of an exemption in the case of a rule **under paragraph (1)** requiring the ban or phase-out of a chemical substance shall not exceed 5 years.

"(e) Immediate Effect.—The Administrator may declare a proposed rule under subsection (d)(1) to be effective on publication of the rule in the Federal Register and until the effective date of final action taken respecting the rule, if—

"(1) the Administrator determines that—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to the proposed rule or any combination of those activities is likely to result in a risk of serious or widespread injury to health or the environment before the effective date; and

"(B) making the proposed rule so effective is necessary to protect the public interest; and

"(2) in the case of a proposed rule to prohibit the manufacture, processing, or distribution in commerce of a chemical substance or mixture because of the risk determined under paragraph (1)(A), a court has granted relief in an action under section 7 with respect to that

risk associated with the chemical substance or mixture.

"(f) Final Agency Action.—Under this section and subject to section 18—

"(1) a safety determination, and the associated safety assessment, for a chemical substance that the Administrator determines under subsection (c) meets the safety standard, shall be considered to be a final agency action, effective beginning on the date of issuance of the final safety determination; and

"(2) a final rule promulgated under subsection (d)(1), and the associated safety assessment and safety determination that a chemical substance does not meet the safety standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule."; and

(4) in subsection (g) (as redesignated by paragraph (2))—

(A) by striking paragraph (4); and

(B) by redesignating paragraph (5) as paragraph (4).

SEC. 9. IMMINENT HAZARDS.

Section 7 of the Toxic Substances Control Act (15 U.S.C. 2606) is amended—

(1) by striking subsection (a) and inserting the following:

"(a) Civil Actions.—

"(1) IN GENERAL.—The Administrator may commence a civil action in an appropriate United States district court for—

"(A) seizure of an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture;

"(B) relief (as authorized by subsection (b)) against any person that manufactures, processes, distributes in commerce, uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture; or

"(C) both seizure described in subparagraph (A) and relief described in subparagraph (B).

"(2) RULE, ORDER, OR OTHER PROCEEDING.—A civil action may be commenced under this paragraph, notwithstanding—

"(A) the existence of a decision, rule, consent agreement, or order by the Administrator under section 4, 4A, 5, or 6 or title IV or VI; or

"(B) the pendency of any administrative or judicial proceeding under any provision of this Act.";

(2) in subsection (b)(1), by striking "unreasonable";

(3) in subsection (d), by striking "section 6(a)" and inserting "section 6(d)"; and

(4) in subsection (f), in the first sentence, by striking "and unreasonable".

SEC. 10. INFORMATION COLLECTION AND REPORTING.

Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amended—

(1) in subsection (a)—

(A) in paragraph (3)(A)(ii)(I)—

(i) by striking "5(b)(4)" and inserting "5";

(ii) by inserting "section 4 or" after "in effect under"; and

(iii) by striking "5(e)," and inserting "5(d)(4);"; and

(B) by adding at the end the following:

"(4) RULES.—

"(A) DEADLINE.—

"(i) IN GENERAL.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall promulgate rules requiring the maintenance of records and the reporting of **additional** information known or reasonably ascertainable by the person making the report, including rules ~~requiring~~ **applicable to** processors ~~to report information,~~ so that the Administrator has the information necessary to carry out ~~sections 4 and 6~~ **this title**.

Commented [S41]: Per TA, changes in this clause made to further clarify and distinguish this authority from the existing authority under subsection (a)(1).

"(ii) MODIFICATION OF PRIOR RULES.—In carrying out this subparagraph, the Administrator may modify, as appropriate, rules promulgated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(B) CONTENTS.—The rules promulgated pursuant to subparagraph (A)—

"(i) may impose different reporting and recordkeeping requirements on manufacturers and processors; and

"(ii) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported.

"(C) ADMINISTRATION.—In implementing the reporting and recordkeeping requirements under this paragraph, the Administrator shall take measures—

"(i) to limit the potential for duplication in reporting requirements;

"(ii) to minimize the impact of the rules on small manufacturers and processors; and

"(iii) to apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this **title.**"; ~~title.~~

~~"(5) Guidance.—The Administrator shall develop guidance relating to the information required to be reported under the rules promulgated under this subsection.";~~

(2) in subsection (b), by adding at the end the following:

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

"(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

"(I) cement, Portland, chemicals, CAS No. 65997–15–1;

"(II) cement, alumina, chemicals, CAS No. 65997–16–2;

"(III) glass, oxide, chemicals, CAS No. 65997–17–3;

"(IV) frits, chemicals, CAS No. 65997–18–4;

"(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

"(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature conventions, the Administrator shall—

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

"(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) RULES.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator, by rule, shall require manufacturers and processors to notify the Administrator, by

not later than 180 days after the date of promulgation of the rule, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(ii) ACTIVE SUBSTANCES.—The Administrator shall~~, pursuant to paragraph (5)(A),~~ designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(iii) INACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which no notices are received under clause (i) to be inactive substances on the list published under paragraph (1).

"(B) CONFIDENTIAL CHEMICAL ~~SUBSTANCES.—THE RULE PROMULGATED BY THE ADMINISTRATOR~~ SUBSTANCES.—**In promulgating the rule established** pursuant to subparagraph (A) ~~shall require~~**, the Administrator shall—**

~~"(i) the Administrator to~~**"(i)** maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

"(ii) **require** a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

"(iii) **require** the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C).

"(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are ~~notified~~ **asserted** pursuant to subparagraph ~~(A) or identified as active substances under subsection (f)(1).~~**(B).**

"(D) REQUIREMENTS OF REVIEW ~~PLAN.—THE~~ PLAN.—**Under the** review plan under subparagraph (C)**, the Administrator** shall—

"(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

"(ii) ~~require the Administrator,~~ in accordance with section 14—

"(I) ~~to~~ review each substantiation—

"(aa) submitted pursuant to clause (i) to determine if the claim

Commented [S42]: Per TA, unnecessary cross-reference.

Commented [S43]: Per TA, to clarify how inactive substances are to be identified.

Commented [S44]: Per TA, to clarify that only prior, not future, claims are subject to the review plan.

Commented [S45]: Per TA, for clarity in direction being provided to EPA.

warrants protection from disclosure; and

"(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

"(II) approve, modify, or deny each claim; and

"(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the ~~confidentiality~~ claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(iii) encourage manufacturers or processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

"(E) TIMELINE FOR COMPLETION OF REVIEWS.—

"(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

"(ii) CONSIDERATIONS.—

"(I) IN GENERAL.—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of ~~applicable~~ claims needing review and the available resources.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of reviews to be completed over the course of implementation of the plan.

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

"(A) IN GENERAL.—The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).

"(B) ~~UPDATE.—THE ADMINISTRATOR SHALL UPDATE THE LIST OF CHEMICAL SUBSTANCES DESIGNATED AS ACTIVE SUBSTANCES AS SOON AS PRACTICABLE AFTER THE DATE OF PUBLICATION OF THE MOST RECENT DATA REPORTED UNDER—~~

Commented [S46]: Per TA, the Chemical Data Reporting (CDR) data are not a sufficient basis for updating active or inactive chemicals.

~~"(I) PART 711 OF TITLE 40, CODE OF FEDERAL REGULATIONS (OR SUCCESSOR REGULATIONS); AND~~

~~"(II) THE RULES PROMULGATED PURSUANT TO SUBSECTION (A)(4).~~

"~~(C)~~ CHANGE TO ACTIVE STATUS.—

"(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

"(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the inactive substance as confidential, the person shall—

"(I) in the notice submitted under clause (i), assert the claim; and

"(II) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

"(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

"(I) designate the applicable chemical substance as an active substance;

"(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific identity of the chemical substance and approve, modify, or deny the claim;

"(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of ~~not less than~~ 10 years, unless, prior to the expiration of the period—

Commented [S47]: For consistency throughout bill as to length of term for CBI claims.

"(aa) the person notifies the Administrator that the person is withdrawing the ~~confidentiality~~ claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines to be necessary.

"~~(D)~~**"(C)** CATEGORY STATUS.—The list of inactive substances shall not be considered to be a category for purposes of section 26(c).

"(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the rule required under paragraph (4)(A), the Administrator shall designate the chemical substances reported

under part 711 of title 40, Code of Federal Regulations ~~(or successor regulations)~~**(as in effect on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act)**, during the reporting period that most closely preceded the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as the interim list of active substances for the purposes of section 4A.

"(7) PUBLIC ~~PARTICIPATION.—SUBJECT~~ INFORMATION.—**Subject** to this subsection, the Administrator shall make available to the public—

"(A) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—

"(i) an active substance; or

"(ii) an inactive substance;

"(B) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received ~~and approved by the Administrator pursuant to section 14~~; and

"(C) subject to **subsections (f) and (g) of** section 14~~(g)~~, the specific identity of any active substance for which—

"(i) ~~no~~ **a** claim ~~of~~ **for** protection against disclosure of the specific identity of the active ~~substance pursuant to this subsection was received;~~ **chemical substance was not asserted, as required under this subsection or subsection (d) or (f) of section 14;**

"(ii) a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or

"(iii) the time period for protection against disclosure of the specific identity of the active substance has expired.

"(8) LIMITATION.—No person may assert a new claim under this subsection for protection from disclosure of a specific identity of any active or inactive chemical substance for which a notice is received under paragraph (4)(A)(i) or (5)(C)(i) that is not on the confidential portion of the list published under paragraph (1).

"(9) CERTIFICATION.—Under the rules promulgated under this subsection, manufacturers and processors shall be required—

"(A) to certify that each ~~report~~ **notice or substantiation** the manufacturer or processor submits complies with the requirements of the rule, and that any confidentiality claims are true and correct; and

"(B) to retain a record supporting the certification for a period of 5 years beginning on the last day of the submission period.";

(3) in subsection (e)—

(A) by striking "Any person" and inserting the following:

"(1) IN GENERAL.—Any person"; and

Commented [S48]: Per TA, the interim list is a one-time, not ongoing, designation.

Commented [S49]: Per TA, EPA review and approval requirements already apply to such claims, no need to specify that here (as this is not done elsewhere for other claims.

Commented [S50]: 14(f) also includes requirements for EPA review of claims.

Commented [S51]: Per TA, reworded to address the fact that not all CBI chem. id claims will be received under this subsection; e.g., claims for new chemicals and for renewals of claims will be asserted and received under section 14.

Commented [S52]: Per TA, to specify the actual items to be certified.

(B) by adding at the end the following:

"(2) ~~APPLICABILITY.—ANY~~ **ADDITIONAL INFORMATION.—Any** person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of injury to health and the environment."; and

(4) in subsection (f), by striking "For purposes of this section, the" and inserting the following: "In this section:

"(1) ACTIVE SUBSTANCE.—The term 'active substance' means a chemical substance—

"(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(B) that is added to the list published under subsection (b)(1) after that date of enactment; or

"(C) for which a notice is received under subsection (b)(5)(C).

"(2) INACTIVE SUBSTANCE.—The term 'inactive substance' means a chemical substance on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).

"(3) MANUFACTURE; PROCESS.—The".

SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.

Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the first sentence—

(i) by striking "presents or will present an unreasonable risk to health or the environment" and inserting "does not **or will not** meet the safety standard"; and

(ii) by striking "such risk" the first place it appears and inserting "the risk posed by the substance or mixture";

(B) in paragraph ~~(2),~~**(2)—**

(i) in subparagraph (A), by inserting "within the time period specified by the Administrator in the report" after "issues an order";

(ii) in subparagraph (B), by inserting "responds within the time period specified by the Administrator in the report and" before "initiates, within 90 days"; and

(iii) in the matter following subparagraph (B), by striking "section 6 or 7" and inserting "section 6(d) or section 7";

~~and~~

~~(C) in~~**(C) by redesignating** paragraph (3) **as paragraph (6);**

(D) in paragraph (6) (as so redesignated), by striking "section 6 or 7" and

Commented [S53]: Per TA, more apt header.

Commented [S54]: Changes to this section are intended to ensure EPA is to act if another agency to which it refers a potential risk for action does not act. If the referral occurs before EPA has completed a safety determination for the substance, then if the other agency does not act EPA must complete the safety determination and take the appropriate action based on the outcome. If EPA has completed the safety determination for the substance, then if the other agency does not act EPA must take the appropriate action based on the outcome of the determination. Finally, any aspect of the potential risk of a substance identified by EPA that it does not refer to another agency remains EPA's responsibility.

inserting "section 6(d) or 7"; **and**

(E) by inserting after paragraph (2) the following:

"(3) The Administrator shall take the actions described in paragraph (4) if the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which the report was made does not—

"(A) issue the order described in paragraph (2)(A) within the time period specified by the Administrator in the report; or

"(B)(i) respond under paragraph (1) within the time frame specified by the Administrator in the report; and

"(ii) initiate action within 90 days of publication in the Federal Register of the response described in clause (i).

"(4) If an agency to which a report under paragraph (1) does not take the actions described in subparagraphs (A) or (B) of paragraph (3), the Administrator shall—

"(A) if a safety assessment and safety determination for the substance under section 6 has not been completed, complete the safety assessment and safety determination;

"(B) if the Administrator has determined or determines that the chemical substance does not meet the safety standard, initiate action under section 6(d) with respect to the risk; or

"(C) take any action authorized or required under section 7, as appropriate.

"(5) This subsection shall not relieve the Administrator of any obligation to complete a safety assessment and safety determination or take any required action under section 6(d) or 7 to address risks from the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of those activities, that are not identified in a report issued by the Administrator under paragraph (1).";

(2) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and inserting "Health and Human Services"; and

(3) by adding at the end the following:

"(e) Exposure Information.—If the Administrator obtains information related to exposures or releases of a chemical substance that may be prevented or reduced under another Federal law, including laws not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.".

SEC. 12. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA.

Section 10 of the Toxic Substances Control Act (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".

SEC. 13. EXPORTS.

Section 12 of the Toxic Substances Control Act (15 U.S.C. 2611) is amended—

(1) in subsection (a), by striking paragraph (2) and inserting the following:

"(2) EXCEPTION.—Paragraph (1) shall not apply ~~to~~ **to—**

"(A) any **new** chemical substance that the Administrator ~~determines—~~ **determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors;**

~~"(A) under section 5 is not likely to meet the safety standard; or~~**"(B) any chemical substance that the Administrator determines presents or will present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; or**

~~"(B) under section 6 does not meet the safety standard.~~**"(C) any chemical substance that—**

~~"(3) Waivers.—For~~**"(i) the Administrator determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; and**

"(ii) is subject to restriction under section 5(d)(4).

"(3) WAIVERS FOR CERTAIN MIXTURES AND ARTICLES.—For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—

"(A) determine that paragraph (1) shall not apply to the mixture or article; or

"(B) establish a threshold concentration in a mixture or article at which paragraph (1) shall not apply.

"(4) TESTING.—The Administrator may require testing under section 4 of any chemical substance or mixture exempted from this Act under paragraph (1) for the purpose of determining whether the chemical substance ~~or mixture~~ meets the safety standard within the United States.";

(2) by striking subsection (b) and inserting the following:

"(b) Notice.—

"(1) IN GENERAL.—A person shall notify the Administrator that the person is exporting or intends to export to a foreign country—

"(A) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 5 is not likely to meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(B) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 6 does not meet the safety standard and for

Commented [S55]: Per TA, to clarify that, while the safety standard applies to the chemical substance as a whole, the issue under section 12(a) of TSCA is whether the *exported portion* of a chemical is likely to, or does or will, present a risk in the US and should therefore not be exempted from TSCA pursuant to paragraph (1).

Commented [S56]: Per TA, more apt header.

Commented [S57]: Per TA, mixtures are not subject to the safety standard.

which a prohibition or other restriction has been proposed or established under that section;

"(C) a chemical substance for which the United States is obligated by treaty to provide export notification;

"(D) a chemical substance or mixture **containing a chemical substance** subject to a **proposed or promulgated** significant new use rule, or a prohibition or other restriction pursuant to a rule, order, or consent agreement in effect under this Act; ~~or~~

"(E) a chemical substance or mixture for which the submission of information is required under section 4**; or**

"(F) a chemical substance or mixture for which an action is pending or for which relief has been granted under section 7.~~.~~

Commented [S58]: To track current TSCA.

Commented [S59]: To track current TSCA.

"(2) RULES.—

"(A) IN GENERAL.—The Administrator shall promulgate rules to carry out paragraph (1).

"(B) CONTENTS.—The rules promulgated pursuant to subparagraph (A) shall—

"(i) include such exemptions as the Administrator determines to be appropriate, which may include exemptions identified under section 5(h); and

"(ii) indicate whether, or to what extent, the rules apply to articles containing a chemical substance or mixture described in paragraph (1).

"(3) NOTIFICATION.—The Administrator shall submit to the government of each country to which a chemical substance or mixture is exported—

"(A) for a chemical substance or mixture described in subparagraph (A), (B), ~~or~~(D)**, or (F)** of paragraph (1), a notice of the determination, rule, order, consent agreement, **action, relief, or** requirement~~, or designation~~;

Commented [S60]: Conforming changes to incorporate above addition of subparagraph (F).

"(B) for a chemical substance described in paragraph (1)(C), a notice that satisfies the obligation of the United States under the applicable treaty; and

"(C) for a chemical substance or mixture described in paragraph (1)(E), a notice of availability of the information on the chemical substance or mixture submitted to the Administrator."; and

(3) in subsection (c)—

(A) by striking paragraph (3); and

(B) by redesignating paragraphs (4) through (6) as paragraphs (3) through (5), respectively.

SEC. 14. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information, or information that is the subject of subsection (g)(3), through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer ~~and specific~~.

"(7) Specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

~~"(7)~~**"(8)** Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, **if** ~~if—~~

~~"(A)~~ the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5~~; and~~

~~"(B) the claim—~~

~~"(i) is not subject to an exception under subsection (e); or~~

~~"(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (f)(2) or (g)~~.

"(c) Information Not Protected From ~~Disclosure.—Notwithstanding~~ **Disclosure.—**

"(1) IN GENERAL.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

~~"(1)~~**"(A)** INFORMATION FROM HEALTH AND SAFETY STUDIES.—

Commented [S61]: Per TA, deleted because these requirements apply to all CBI claims, not just chemical identity claims, and stating under section 6(a)(4)ished bdivision of a State adding here ons.formation.ection 113paragraphbsection (a)_____here could call that into question.

Commented [S62]: Reformatting and clean-up in this paragraph for clarity.

~~"(A)~~**"(i)** IN GENERAL.—Subject to ~~subparagraph (B), subsection (a) does not prohibit the disclosure of~~ **clause (ii)**—

~~"(i)~~**"(I)** any health and safety study that is submitted under this Act with respect to—

~~"(I)~~**"(aa)** any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

~~"(II)~~**"(bb)** any chemical substance or mixture for which—

~~"(aa)~~**"(AA)** testing is required under section 4; or

~~"(bb)~~**"(BB)** a notification is required under section 5; or

~~"(ii)~~**"(II)** any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in ~~subclause (I) or (II) of clause (i).~~ **item (aa) or (bb) of subclause (I).**

~~"(B)~~**"(ii)** EFFECT OF ~~PARAGRAPH.—NOTHING~~ **SUBPARAGRAPH.—Nothing** in this ~~paragraph~~ **subparagraph** authorizes the release of any information that discloses—

~~"(i)~~**"(I)** a process used in the manufacturing or processing of a chemical substance or mixture; or

~~"(ii)~~**"(II)** in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

~~* 4 "(2) Certain requests.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.~~

~~"(3)~~**"(B)** OTHER INFORMATION NOT PROTECTED FROM ~~DISCLOSURE.—THE FOLLOWING INFORMATION IS NOT PROTECTED FROM DISCLOSURE UNDER THIS SECTION:~~ **DISCLOSURE.—**

~~"(A)~~**"(i)** For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

~~"(B)~~**"(ii)** A safety assessment developed, or a safety determination made, under section 6.

~~"(C)~~**"(iii)** Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

Commented [S63]: Unnecessary, already in paragraph (1) lead-in.

Commented [S64]: Per TA, moved to become paragraph (4) below and apply to this subsection.

Commented [S65]: Unnecessary, already in paragraph (1) lead-in.

~~"(D)~~**"(iv)** A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

~~"(4)~~**"(2)** MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is ~~otherwise~~ eligible for protection under this section and ~~contained in a submission of~~ **is submitted with** information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

~~"(5)~~**"(3)** BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.

** **4** ~~"(2)~~**"(4)** CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is ~~described in paragraph (1) that is not described in paragraph (1)(B)~~ **subject to disclosure under this subsection**, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(d) Requirements for Confidentiality Claims.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A)

for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name shall—

"(i) ~~conform~~ **be consistent** with guidance ~~prescribed~~ **issued** by the Administrator under paragraph (3)(A); and

"(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are considered to be confidential; and

"(II) the disclosure of which would be likely to **cause substantial** harm **to** the competitive position of the person.

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in ~~paragraphs (1) through (7) of~~ subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and **consistent with the** guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the ~~information that has been submitted is~~ **statement required to assert a claim submitted pursuant to paragraph (1)(B) and any information required to substantiate a claim submitted pursuant to paragraph (2) are** true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a)—

"(1) shall be disclosed if the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) shall be disclosed if the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) shall be disclosed if the Administrator determines that disclosure is necessary to

Commented [S66]: Per TA, to better reflect role of guidance.

Commented [S67]: Per TA, to reflect FOIA requirement at 5 USC 552(b)(4).

Commented [S68]: Per TA, to better specify preecisely what is subject to certification.

protect health or the environment;

"(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, **if** ~~if~~—

~~"(A)~~ 1 or more applicable agreements with the Administrator that ~~conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; ~~and~~

~~"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;~~

Commented [S69]: All notification requirements are now consolidated in subsection (g)(2).

"(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement ~~shall conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) shall be disclosed if the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

"(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION ~~PROTECTED~~ **NOT SUBJECT TO TIME LIMIT FOR PROTECTION** FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information **described in subsection (b)** that meets the requirements of ~~subsection (d) for a period of 10 years, unless, prior to the expiration of the period~~ **subsections (a) and (d), unless—**

Commented [S70]: For clarity by distinguishing between information subject and not subject to time limits.

~~"(i) an affected person~~ **"(i) the person that asserted the claim** notifies the Administrator that the person is withdrawing the ~~confidentiality~~ claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the ~~need for protection from disclosure can no longer be substantiated~~ **information does not qualify or no longer qualifies for protection against disclosure under subsection (a)**, in which case the Administrator shall take ~~the~~ **any** actions ~~described in~~ **required under** subsection (g)(2).

"(B) **INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information, other than information described in subsection (b), that**

meets the requirements of subsections (a) and (d) for a period of 10 years, unless, prior to the expiration of the period—

"(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)(2).

"(C) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, a person reasserting the relevant claim shall submit to the Administrator a ~~statement~~ **request for extension** substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date ~~that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—~~ **of expiration of the period described in subparagraph (B), the Administrator shall, in accordance with subsection (g)(1)(C)—**

"(aa) review the request **submitted under subclause (I)**;

"(bb) make a determination regarding whether the ~~information~~ **claim** for which the request ~~is made~~ **was submitted** continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of ~~not more than~~ 10 years; or

"(BB) deny the ~~claim.~~ **request.**

~~"(C)~~**"(D)** NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph ~~(B)~~**(C)**, if the Administrator determines that the relevant ~~statement~~ **request** under subparagraph ~~(B)(ii)(I)~~ **(C)(ii)(I)—**

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection **of information** against disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require

Commented [S71]: To ensure that FOIA trade secret provisions apply to protected claims.

Commented [S72]: Throughout the remainder of this subsection, the term "request" is used to refer to these requests for extensions.

Commented [S73]: For consistency as to length of period of protection throughout the section.

any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating rules pursuant to section 6(d)~~, subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d)~~.

Commented [S74]: Per TA, redundant with paragraph (1) above.

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection ~~from~~ **of information against** disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) as necessary to ~~comply~~ **determine whether the information qualifies for an exemption from disclosure in connection** with a request for information received by the Administrator under section 552 of title 5, United States Code;

Commented [S75]: Per TA, here and in (ii), to more clearly specify the action to be taken or finding to be made by EPA pursuant to such a request.

"(ii) if ~~information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met~~ **the Administrator has a reasonable basis to believe that the information does not qualify for protection against disclosure under subsection (a)**; or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator ~~on expiration of the period for appeal under subsection (g)(4), that has~~ **or** expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

Commented [S76]: Per TA, as this proviso is not included in other release provisions, and subsection (g)(3) serves this function already.

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

"(B) **REASONS FOR DENIAL OR MODIFICATION.—If Administrator denies or modifies a claim or request under subparagraph (A)** ~~Denial or modification.—~~

~~"(i) In general.—Except as provided in subsections (c) and (f),~~ the Administrator shall **provide to the person that submitted the claim or request** ~~deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).~~

Commented [S77]: Per TA, this clause is unnecessary; it's already the case that EPA must approve a claim if it meet the requirements of (a) and (d).

~~"(ii) Reasons for denial or modification.—The Administrator shall provide to a person that has submitted a claim described in clause (i)~~ a written statement of the reasons for the denial or modification of the claim **or request**.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection ~~(b)(7)~~**(b)(8)**, review all claims **or requests** under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims **or requests** for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim **or request** for protection against disclosure or extension

under this section shall not be the basis for denial or elimination of a claim **or request** for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim **or request** under paragraph (1), **intends to release information pursuant to subsection (e),** or promulgates a rule under section 6(d) establishing a ban or phase-out of a chemical substance, the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

Commented [S78]: Per TA, to be consistent and clear that, as under current TSCA, exceptions may still be subject to notification, per this paragraph.

"(B) RELEASE OF INFORMATION.—**Except** ~~information.—~~

~~"(i) In general.—Except~~ as provided in ~~clause (ii)~~ **subparagraph (C)**, the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

~~"(ii)~~**"(C)** EXCEPTIONS.—

Commented [S79]: Consolidates all exceptions to notification in one subparagraph.

~~"(I)~~**"(i)** IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim **or request** receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

"(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information under paragraphs (4) and (6) of subsection (e), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

"(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

"(I) for the disclosure of ~~"(II) No notification.—For~~ information under paragraph (1), (2), ~~(6),~~(7), or (9) of subsection (e)~~, no prior notification shall be necessary.~~**; or**

"(II) for the disclosure of information for which—

"(aa) a notice under subsection (f)(1)(C)(i) was received; and

"(bb) no request was received by the Administrator on or before the date of expiration of the period for which protection from disclosure applies.

"(3) REBUTTABLE PRESUMPTION.—

"(A) IN GENERAL.—With respect to notifications provided by the Administrator **under paragraph (2) with respect to information pertaining to a chemical substance subject to a rule as described in** pursuant to subsection ~~(c)(5)~~**(c)(3)**, there shall be a rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section

Commented [S80]: To clarify which notice pertaining to which chemical this provision applies to.

6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.

"(B) REQUEST FOR NONDISCLOSURE.—A person that receives a notification under paragraph (2) with respect to the information described in subparagraph (A) may submit to the Administrator, before the date on which the information is to be released **pursuant to paragraph (2)(B)**, a request with supporting documentation describing why the person believes some or all of that information should not be disclosed.

Commented [S81]: Per TA, to specify the date referred to.

"(C) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—Not later than 30 days after the Administrator receives a request under subparagraph (B), the Administrator shall determine, at the discretion of the Administrator, whether the documentation provided by the person making the request rebuts or does not rebut the presumption described in subparagraph (A), for all or a portion of the information that the person has requested not be disclosed.

"(ii) OBJECTIVE.—The Administrator shall make the determination with the objective of ensuring that information relevant to protection of health and the environment is disclosed to the maximum extent practicable.

"(D) TIMING.—Not later than 30 days after making the determination described in subparagraph (C), the Administrator shall make public the information the Administrator has determined is not to be protected from disclosure.

"(E) NO TIMELY REQUEST RECEIVED.—If the Administrator does not receive, before the date on which the information described in subparagraph (A) is to be released **pursuant to paragraph (2)(B)**, a request pursuant to subparagraph (B), the Administrator shall promptly make public all of the information.

Commented [S82]: Per TA, to specify the date referred to.

"(4) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released **pursuant to paragraph (2)(B)**, the person may bring an action to restrain disclosure of the information in—

Commented [S83]: Per TA, to specify the date referred to.

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

~~"(5) Administration.—In carrying out this subsection, the Administrator shall use the procedures described in part 2 of title 40, Code of Federal Regulations (or successor regulations).~~

Commented [S84]: Per TA, this provision has no effect, since it just says that EPA will follow whatever rules it has in place; and it does not specify all relevant regulations.

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information ~~submitted to~~ **reported to or otherwise obtained by** the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

"(2) ~~PRIOR ACTIONS.—NOTHING~~ **ACTIONS PRIOR TO PROMULGATION OF RULES.—Nothing** in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

Commented [S85]: Clearer header.

SEC. 15. PROHIBITED ACTS.

Section 15 of the Toxic Substances Control Act (15 U.S.C. 2614) is amended by striking paragraph (1) and inserting the following:

"(1) fail or refuse to comply with—

"(A) any rule promulgated, consent agreement entered into, or order issued under section 4;

"(B) any requirement under section 5 or 6;

"(C) any rule promulgated, consent agreement entered into, or order issued under section 5 or 6; or

"(D) any requirement of, or any rule promulgated or order issued pursuant to title II;".

SEC. 16. PENALTIES.

Section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) is amended—

(1) in subsection (a)(1)—

(A) in the first **sentence,** ~~sentence—~~

~~(i) by inserting "this Act or a rule or order promulgated or issued pursuant to this Act, including" after "a provision of"; and~~

Commented [S86]: Per TA, already covered in section 15.

~~(ii)~~ by striking "$25,000" and inserting "$37,500"; and

(B) in the second sentence, by striking" violation of section 15 or 409" and inserting "violation of this Act"; and

(2) in subsection (b)—

(A) by striking "Any person who" and inserting the following:

"(1) IN GENERAL.—Any person that";

~~(B) by striking "section 15 or 409" and inserting "this Act";~~

Commented [S87]: Per TA, already covered in section 15.

~~(C)~~ by striking "$25,000" and inserting "$50,000"; and

~~(D)~~**(C)** by adding at the end the following:

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of ~~this Act~~ **section 15 or 409**, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

"(B) ORGANIZATIONS.—An organization that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation.

~~"(3) Knowledge of imminent danger or injury.—For purposes of determining whether a defendant knew that the violation placed another individual in imminent danger of death or serious bodily injury—~~

~~"(A) the defendant shall be responsible only for actual awareness or actual belief possessed; and~~

~~"(B) knowledge possessed by an individual may not be attributed to the defendant.".~~**"(C) INCORPORATION OF CORRESPONDING PROVISIONS.—Subparagraphs (B) through (F) of section 113(c)(5) of the Clean**

Air Act (42 U.S.C. 7413(c)(5)) shall apply to the prosecution of a violation under this paragraph.".

Commented [S88]: Reference is to provisions of the Clean Air Act addressing knowledge of imminent danger or injury, affirmative defense, and defenses.

SEC. 17. STATE-FEDERAL RELATIONSHIP.

Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following:

"(a) In General.—

"(1) ESTABLISHMENT OR ENFORCEMENT.—Except as provided in subsections (c), (d), (e), (f), and (g), and subject to paragraph (2), no State or political subdivision of a State may establish or continue to enforce any of the following:

"(A) ~~TESTING AND INFORMATION COLLECTION.—~~A **TESTING.—A** statute or administrative action to require the development of information on a chemical substance or category of substances that is reasonably likely to produce the same information required under section 4, 5, or 6 in—

Commented [S89]: Reference to "information collection" was incorrect as this provision deals with development of new information.

"(i) a rule promulgated by the Administrator;

"(ii) a testing consent agreement entered into by the Administrator; or

"(iii) an order issued by the Administrator.

"(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

"(i) found to meet the safety standard and consistent with the scope of the determination made under section 6; or

"(ii) found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

"(C) SIGNIFICANT NEW USE.—A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(2) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of ~~State~~ statutes and administrative actions applicable to specific substances shall not occur until the effective date of the applicable action described in paragraph (1) taken by the Administrator.

"(b) New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions.—

"(1) IN GENERAL.—Except as provided in subsections (c), (d), ~~and~~(e), **(f), and (g),** beginning on the date on which the Administrator defines **and publishes** the scope of a safety assessment and safety determination under section 6(a)(2) and ending on the date on which the Administrator publishes the safety determination **under section 6(a)(4)**, no State or political subdivision of a State may establish a statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical

Commented [S90]: Additional exceptional cases are identified in these subsections.

substance that is a high-priority substance designated under section 4A.

"(2) EFFECT OF SUBSECTION.—

"(A) IN GENERAL.—This subsection does not restrict the authority of a State or political subdivision of a State to continue to enforce any ~~State~~ statute enacted, or administrative action taken, prior to the date on which the Administrator defines **and publishes** the scope of a safety assessment and safety determination under section 6(a)(2).

"(B) LIMITATION.—Subparagraph (A) does not allow a State or political subdivision of a State to enforce any new prohibition or restriction under a ~~State~~ statute or administrative action described in that subparagraph, if the prohibition or restriction is established after the date described in that subparagraph.

"(c) Scope of Preemption.—Federal preemption under subsections (a) and (b) of ~~State~~ statutes and administrative actions applicable to specific substances shall apply only to—

"(1) the chemical substances or category of substances subject to a rule, order, or consent agreement under section 4;

"(2) the uses or conditions of use of such substances that are identified by the Administrator as subject to review in a safety assessment and included in the scope of the safety determination made by the Administrator for the substance, or of any rule the Administrator promulgates pursuant to section 6(d); or

"(3) the uses of such substances that the Administrator has specified as significant new uses and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(d) Exceptions.—

"(1) NO PREEMPTION OF ~~STATE~~ STATUTES AND ADMINISTRATIVE ACTIONS.—

"(A) IN GENERAL.—Nothing in this Act, nor any amendment made by this Act, nor any rule, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

"(i) is adopted or authorized under the authority of any other Federal law or adopted to satisfy or obtain authorization or approval under any other Federal law;

"(ii) implements a reporting, monitoring, disclosure, or other information obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law;

"(iii) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, except to the extent that the action—

"(I) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

Commented [S91]: Throughout, either deleted "state" or added "or political subdivision of a state" to clarify the provisions apply to both.

"(II)(aa) addresses the same hazards and exposures, with respect to the same conditions of use as are included in the scope of the safety determination pursuant to section 6, but is inconsistent with the action of the Administrator; or

"(bb) would cause a violation of the applicable action by the Administrator under section 5 or 6; or

"(iv) subject to subparagraph (B), is identical to a requirement prescribed by the Administrator.

"(B) IDENTICAL REQUIREMENTS.—

"(i) IN GENERAL.—The penalties and other sanctions applicable under ~~State law~~ **a law of a State or political subdivision of a State** in the event of noncompliance with the identical requirement shall be no more stringent than the penalties and other sanctions available to the Administrator under section 16 of this Act.

"(ii) PENALTIES.—In the case of an identical requirement, no **State or political subdivision of a** State may assess a penalty for a specific violation for which the Administrator has already assessed a penalty under section 16, and the Administrator may not assess a penalty under section 16 for a specific violation for which **a State or political subdivision of** a State has already assessed a penalty.

"(2) APPLICABILITY TO CERTAIN RULES OR ORDERS.—Notwithstanding subsection (e)—

"(A) nothing in this section shall be construed as modifying the effect under this section, as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, of any rule or order promulgated or issued under this Act prior to that effective date; and

"(B) with respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 6 prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act with regards to manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance, this section (as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after that effective date, unless the latter rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under **subsection (b) or (c) of** section 4A~~(b)~~ or as an additional priority for safety assessment and safety determination under section 4A(c).

"(e) Preservation of Certain ~~State Law.—~~ **Laws.—**

"(1) IN GENERAL.—Nothing in this Act, subject to subsection (g) of this section, shall—

"(A) be construed to preempt or otherwise affect the authority of a State or political subdivision of a State to continue to enforce any action taken before August 1, 2015, under the authority of a ~~State law~~ **law of the State or political subdivision of the**

State that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance; or

"(B) be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003.

"(2) EFFECT OF SUBSECTION.—This subsection does not affect, modify, or alter the relationship between ~~State and Federal law~~ **Federal law and laws of a State or political subdivision of a State** pursuant to any other Federal law.

"(f) ~~State~~ Waivers.—

"(1) DISCRETIONARY EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator may by rule, exempt from subsection (a), under such conditions as may be prescribed in the rule, a statute or administrative action of that State or political subdivision of the State that relates to the effects of, or exposure to, a chemical substance under the conditions of use if the Administrator determines that—

"(A) compelling State or local conditions warrant granting the waiver to protect health or the environment;

"(B) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(C) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

"(D) based on the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is consistent with sound objective scientific practices, the weight of the evidence, and the best available science.

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

"(A) compliance with the proposed requirement of the State ~~will~~ **or political subdivision of the State would** not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

Commented [S92]: For consistency with (1)(B) above.

"(B) compliance with the proposed requirement **of the State or political subdivision of the State** would not cause a violation of any applicable Federal law, rule, or order; and

"(C) the State or political subdivision of ~~a~~ **the** State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science.

"(3) DETERMINATION OF A ~~STATE~~ WAIVER REQUEST.—The duty of the Administrator to grant or deny a waiver application shall be nondelegable and shall be exercised—

"(A) not later than 180 days after the date on which an application under paragraph (1) is submitted; and

"(B) not later than ~~90~~ **110** days after the date on which an application under paragraph (2) is submitted.

"(4) FAILURE TO MAKE DETERMINATION.—If the Administrator fails to make a determination under paragraph (3)(B) during the ~~90~~ **110**-day period beginning on the date on which an application under paragraph (2) is submitted, the ~~State~~ statute or administrative action **of the State or political subdivision of the State** that was the subject of the application shall not be considered to be an existing statute or administrative action for purposes of subsection (b) by reason of the failure of the Administrator to make a determination.

"(5) NOTICE AND COMMENT.—Except in the case of an application approved under paragraph (9), the application of a State or political subdivision of ~~the~~ **a** State shall be subject to public notice and comment.

"(6) FINAL AGENCY ACTION.—The decision of the Administrator on the application of a State or political subdivision of ~~the~~ **a** State shall be—

"(A) considered to be a final agency action; and

"(B) subject to judicial review.

"(7) DURATION OF **WAIVERS.—A** ~~waivers.—~~

~~"(A) In general.—Except as provided in subparagraph (B), a~~ waiver granted under paragraph (2) or approved under paragraph (9) shall remain in **effect** ~~effect—~~

~~"(i)~~ until such time as the ~~safety assessment and safety determination is completed; or~~ **Administrator publishes the safety determination under section 6(a)(4).**

~~"(ii) subject to subparagraph (B), until judicial review of the failure of the Administrator to make a determination under paragraph (3) is sought under paragraph (8).~~

~~"(B) Reinstatement of waiver.—A waiver described in subparagraph (A)(ii) shall again take effect upon the earlier of—~~

~~"(i) the date of approval by the Administrator of the waiver application;~~

~~"(ii) the effective date of a court order directing the Administrator to approve the waiver application; or~~

~~"(iii) 90~~**"(8) JUDICIAL REVIEW OF WAIVERS.—Not later than 60** days after the date on which ~~judicial review under paragraph (8) is sought.~~

~~"(8) Judicial review of waivers.—Not later than 60 days after the date on which~~ the Administrator makes a determination on an application of a State or political subdivision of ~~the~~ **a** State under paragraph (1) or (2), ~~or not later than 60 days after the date on which the Administrator fails to make a determination under paragraph (3),~~ any person may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.

"(9) APPROVAL.—

"(A) ~~IN GENERAL.—IF~~ **AUTOMATIC APPROVAL.—**

"(i) If the Administrator fails to meet the deadline **established** under section

Commented [S93]: Modified time period to provide a 10-day window to file a civil action for EPA's failure to fulfill a mandatory duty pursuant to TSCA section 20. See accompanying change in paragraph (9)(A)(ii) below.

Commented [S94]: Same as preceding comment.

Commented [S95]: Changes made to eliminate on-again, off-again waiver applicability.

6(a)(4) (including an extension granted under section 6(a)(6)), ~~or the deadline established under paragraph (3)(B),~~ the application of a State or political subdivision of a State under paragraph (2) shall be automatically approved.

"(ii) If the Administrator fails to meet the deadline established under paragraph (3)(B), the application of a State or political subdivision of a State under paragraph (2) shall be automatically approved, effective on the date that is 10 days after the deadline.

"(B) REQUIREMENTS.—Notwithstanding paragraph (6), approval of a waiver application under subparagraph (A) for failure to meet the deadlines under section 6(a)(4) (including an extension granted under section 6(a)(6)) **or paragraph (3)(B)** shall not be considered final agency action or be subject to judicial review or public notice and comment.

~~"(10) Judicial review of low-priority decisions.—~~

~~"(A) In general.—Not later than 60 days after the publication of a designation under section 4A(b)(4), any person may commence a civil action to challenge the designation.~~

~~* 5 "(B) Jurisdiction.—The United States Court of Appeals for the District of Columbia Circuit shall have exclusive jurisdiction over a civil action filed under this paragraph.~~

"(g) Savings.—

"(1) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF OR CRIMINAL CONDUCT.—

"(A) IN GENERAL.—Nothing in this Act, nor any amendment made by this Act, nor any safety standard, rule, requirement, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall be construed to preempt, displace, or supplant any state or Federal common law rights or any state or Federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.

"(B) CLARIFICATION OF NO PREEMPTION.—Notwithstanding any other provision of this Act, nothing in this Act, nor any amendments made by this Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any State law, maritime law, or Federal common law or statutory theory.

"(2) NO EFFECT ON PRIVATE REMEDIES.—

"(A) IN GENERAL.—Nothing in this Act, nor any amendments made by this Act, nor any rules, regulations, requirements, safety assessments, safety determinations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.

"(B) AUTHORITY OF COURTS.—This Act does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this Act or rules,

Commented [S96]: Broke out the missed (3)(B) waiver deadline into its own clause in order to apply a 10-day lag between the deadline and the automatic approval to provide a window for anyone seeking to file a civil action for EPA's failure to fulfill a mandatory duty pursuant to TSCA section 20. See accompanying change in paragraph (3)(B) above.

Commented [S97]: See addition to section 20(b)(2) to waive the 60-day advance notice requirement to bring a civil action to compel an EPA decision on a waiver request for which the deadline has passed.

Commented [S98]: Moved to section on Judicial Review, section 19(a)(3).

regulations, requirements, standards of performance, safety assessments, scientific assessments, or orders issued pursuant to this Act.".

SEC. 18. JUDICIAL REVIEW.

Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph ~~(A),~~**(A)**—

(I) in the first sentence—

(aa) by striking "Not" and inserting "Except as otherwise provided in this title, not";

(bb) by striking "section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting ~~"section 4(a), 5(d), 6(c), 6(d), 6(g), or 8, or title II or IV"; and~~**"this title or title II or IV, or an order under section 6(c)(1)(A)"; and**

~~(ii) in subparagraph (B),~~**(cc) by striking "judicial review of such rule" and inserting "judicial review of such rule or order"; and**

(II) in the second sentence, by striking "such a rule" and inserting "such a rule or order"; and

(ii) in subparagraph (B)—

(I) by striking "Courts" and inserting "Except as otherwise provided in this title, courts"; and

(II) by striking "an order issued under subparagraph (A) or (B) of section 6(b)(1)" and inserting "an order issued under this title"; ~~and~~

(B) in paragraph (2), in the ~~first~~ **second** sentence, by striking ~~"paragraph (1)(A)" and inserting "paragraph (1)"~~**"the filing of the rulemaking record of proceedings on which the Administrator based the rule being reviewed" and inserting "the filing of the record of proceedings on which the Administrator based the rule or order being reviewed"**; and

(C) by striking paragraph (3) ~~, and~~ **and inserting the following:**

"(3) JUDICIAL REVIEW OF LOW-PRIORITY DECISIONS.—

"(A) IN GENERAL.—Not later than 60 days after the publication of a designation under section 4A(b)(4), or a designation under section 4A(b)(8) of a chemical substance as a low-priority substance, any person may commence a civil action to challenge the designation.

** 5 "(B) JURISDICTION.—The United States Court of Appeals for the District of Columbia Circuit shall have exclusive jurisdiction over a civil action filed under this ~~paragraph.~~ **paragraph."; and**

(2) in subsection (c)(1)(B)—

Commented [S99]: Per TA, changes below are to simplify language and incorporate all relevant cross-references.

Commented [S100]: To ensure positive safety determinations are subject to judicial review under this section. Other changes here and in (B) are conforming.

Commented [S101]: Moved here from section 18(f)(10) because the provision deals with judicial review, not federal-state relationship.

(A) in clause (i)—

(i) by striking "section 4(a), 5(b)(4), 6(a), or 6(e)" and inserting "section 4(a), ~~5(d), 6(d), or 6(g)~~" **6(d), or 6(g), or an order under section 6(c)(1)(A)**"; and

(ii) by striking "evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;" and inserting "evidence (including any matter) in the rulemaking record, taken as a whole; and"; and

(B) by striking clauses (ii) and (iii) and the matter following clause (iii) and inserting the following:

"(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule, except as part of the rulemaking record, taken as a whole.".

Commented [S102]: To ensure positive safety determinations are subject to the substantial evidence standard of judicial review under this subsection.

SEC. 19. CITIZENS' CIVIL ACTIONS.

Section 20 of the Toxic Substances Control Act (15 U.S.C. 2619) is amended—

(1) in subsection (a)(1), by striking "or order issued under section 5" and inserting "or order issued under section 4 or 5"; and

(2) in subsection (b)—

(A) in paragraph (1)(B), by striking "or" at the end;

(B) in paragraph (2), by striking the period at the end and inserting ", except that no prior notification shall be required in the case of a civil action brought to compel a decision by the Administrator pursuant to section 18(f)(3)(B); or"; and

(C) by adding at the end the following:

"(3) in the case of a civil action brought to compel a decision by the Administrator pursuant to section 18(f)(3)(B), after the date that is 60 days after the deadline specified in section 18(f)(3)(B).".

Commented [S103]: To ensure test orders are subject to this section.

Commented [S104]: Change needed to ensure timely ability to compel an EPA decision on a preemption waiver request from a state.

Commented [S105]: Limits the waiving of the advance notification requirement to civil actions for missed interim waiver decision deadlines

Commented [S106]: Adds a requirement that any civil action to compel a decision on an interim waiver application after EPA misses the deadline must be filed within 60 days of the deadline.

SEC. 20. CITIZENS' PETITIONS.

Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an order under section 4 or 5(d)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "an order under section 4 or 5(d)"; and

(B) in paragraph (4), by striking subparagraph (B) and inserting the following:

"(B) DE NOVO PROCEEDING.—

"(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to ~~promulgate~~ **issue** a rule pursuant to section 4, 5, 6, or 8 or issue an order under section 4 or 5(d), the petitioner shall be provided an opportunity to have the

Commented [S107]: Per TA, to track current TSCA.

petition considered by the court in a de novo proceeding.

"(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a rule or order under section 4, the information ~~available to the Administrator is insufficient for the Administrator to perform an action described in section 4, 4A, 5, or 6(d);~~ **is needed for a purpose identified in section 4(a);**

"(bb) in the case of a petition to issue an order under section 5(d), ~~there is a reasonable basis to conclude that~~ the chemical substance is not likely to meet the safety standard;

"(cc) in the case of a petition to initiate a proceeding for the issuance of a rule under section 6(d), ~~there is a reasonable basis to conclude that~~ the chemical substance ~~will~~ **does** not meet the safety standard; or

"(dd) in the case of a petition to initiate a proceeding for the issuance of a rule under section 8, there is a reasonable basis to conclude that the rule is necessary to protect health or the environment or ensure that the chemical substance meets the safety standard.

"(II) DEFERMENT.—The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

"(aa) the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act; and

"(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.".

SEC. ~~20~~ **21**. EMPLOYMENT EFFECTS.

Section 24(b)(2)(B)(ii) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by striking "section 6(c)(3)," and inserting "the applicable requirements of this Act;".

SEC. ~~21.~~ **22.** STUDIES.

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.

SEC. ~~22.~~ **23.** ADMINISTRATION.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

Commented [S108]: Per TA, references the range of purpose for which testing can be required under section 4.

Commented [S109]: Per TA, to conform with the application of the safety standard under section 5 as revised by the bill.

Commented [S110]: Per TA, to conform with the application of the safety standard under section 6 as revised by the bill.

(1) by striking subsection (b) and inserting the following:

"(b) Fees.—

"(1) IN GENERAL.—The Administrator shall establish, not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, by rule—

"(A) the payment of 1 or more reasonable fees as a condition of submitting a notice or requesting an exemption under section 5; **and**

"(B) the payment of 1 or more reasonable fees by a manufacturer or processor that—

"(i) is required to submit a notice pursuant to the rule promulgated under section 8(b)(4)(A)(i) identifying a chemical substance as active;

"(ii) is required to submit a notice pursuant to section 8(b)(5)(B)(i) changing the status of a chemical substance from inactive to active;

"(iii) is required to report information pursuant to the rules promulgated under **paragraph (1) or (4) of** section 8(a)~~(4); and~~**; or**

"(iv) manufactures or processes a chemical substance subject to a safety assessment and safety determination pursuant to section 6.

"(2) UTILIZATION AND COLLECTION OF FEES.—The Administrator shall—

"(A) utilize the fees collected under paragraph (1) only to defray costs associated with the actions of the Administrator—

"(i) to collect, process, review, provide access to, and protect from disclosure (where appropriate) information on chemical substances under this Act;

"(ii) to review notices and make determinations for chemical substances under paragraphs (1) and (3) of section 5(d) and impose any necessary restrictions under section 5(d)(4);

"(iii) to make prioritization decisions under section 4A;

"(iv) to conduct and complete safety assessments and determinations under section 6; and

"(v) to conduct any necessary rulemaking pursuant to section 6(d);

"(B) insofar as possible, collect the fees described in paragraph (1) in advance of conducting any fee-supported activity;

"(C) deposit the fees in the Fund established by paragraph (4)(A); and

"(D) **insofar as possible,** not collect excess fees or retain a significant amount of unused fees.

"(3) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—In setting fees under this section, the Administrator shall—

~~"(A) take into account the cost to the Administrator of conducting the activities described in paragraph (2);~~

Commented [S111]: Per TA, to incorporate persons subject to reporting under section 8(a)(1).

Commented [S112]: To clarify these are independent clauses any one of which applies.

Commented [S113]: Per TA, redundant.

"~~(B)~~ prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

"~~(C)~~**"(B)** set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to defray approximately 25 percent of the costs of conducting the activities identified in paragraph (2)(A), not to exceed $18,000,000~~, not including fees under subparagraph (E) of this paragraph;~~;

Commented [S114]: Per TA, deletion here and addition in (D) below are to make clear that fees for additional priorities do not count toward the cap.

"~~(D)~~**"(C)** reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

"~~(E)~~**"(D) notwithstanding subparagraph (B) and paragraph (4)(D),** for substances designated as additional priorities pursuant to section 4A(c), establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the safety assessment and safety determination under section 6, except that for substances subject to section 4A(c)(3), the Administrator shall establish the fee at a level sufficient to defray 50 percent of those costs;

"~~(F)~~**"(E)** prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) or subchapter III of chapter 5 of title 5, United States Code, is applicable with respect to such meetings;

"~~(G)~~**"(F)** beginning with the fiscal year that is 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives **pursuant to subparagraph (E)**, increase or decrease the fees established under paragraph (1) as necessary—

"(i) to ensure that funds deposited in the Fund are sufficient to conduct the activities identified in paragraph (2)(A) and **defray** the full **costs and the** 50-percent portion of the costs of safety assessments and safety determinations ~~pursuant to~~ **specified in** subparagraph ~~(E),~~**(D);** and

"(ii) to account for inflation;

"~~(H)~~**"(G)** adjust fees established under paragraph (1) as necessary to vary on account of differing circumstances, including reduced fees or waivers in appropriate circumstances, to reduce the burden on manufacturing or processing, remove barriers to innovation, or where the costs to the Administrator of collecting the fees exceed the fee revenue anticipated to be collected; and

"~~(I)~~**"(H)** if a notice submitted under section 5 is refused or subsequently withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

"(4) TSCA IMPLEMENTATION FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the 'TSCA Implementation Fund' (referred to in this subsection as the 'Fund'), consisting of—

"(i) such amounts as are deposited in the Fund under paragraph (2)(C); and

"(ii) any interest earned on the investment of amounts in the Fund; and

"(iii) any proceeds from the sale or redemption of investments held in the Fund.

"(B) CREDITING AND AVAILABILITY OF FEES.—

"(i) IN GENERAL.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation.

"(ii) REQUIREMENTS.—Fees collected under this section shall not—

"(I) be made available or obligated for any purpose other than to defray the costs of conducting the activities identified in paragraph (2)(A);

"(II) otherwise be available for any purpose other than implementation of this Act; and

"(III) so long as amounts in the Fund remain available, be subject to restrictions on expenditures applicable to the Federal government as a whole.

"(C) UNUSED FUNDS.—Amounts in the Fund not currently needed to carry out this subsection shall be—

"(i) maintained readily available or on deposit;

"(ii) invested in obligations of the United States or guaranteed by the United States; or

"(iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

"(D) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2015) of the Office of Pollution Prevention and Toxics of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for covered functions for fiscal year 2015 (excluding the amount of any fees appropriated for the fiscal year).

"(5) AUDITING.—

"(A) FINANCIAL STATEMENTS OF AGENCIES.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of an executive agency.

"(B) COMPONENTS.—The annual audit required under sections 3515(b) and 3521 of that title of the financial statements of activities under this subsection shall include an analysis of—

"(i) the fees collected under paragraph (1) and disbursed;

"(ii) compliance with the deadlines established in section 6 of this Act;

"(iii) the amounts budgeted, appropriated, collected from fees, and disbursed to

meet the requirements of sections 4, 4A, 5, 6, 8, and 14, including the allocation of full time equivalent employees to each such section or activity; and

"(iv) the reasonableness of the allocation of the overhead associated with the conduct of the activities described in paragraph (2)(A).

"(C) INSPECTOR GENERAL.—The Inspector General of the Environmental Protection Agency shall—

"(i) conduct the annual audit required under this subsection; and

"(ii) report the findings and recommendations of the audit to the Administrator and to the appropriate committees of Congress.

"(6) TERMINATION.—The authority provided by this section shall terminate at the conclusion of the fiscal year that is 10 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, unless otherwise reauthorized or modified by Congress.";

(2) in subsection (e), by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services"; and

(3) adding at the end the following:

"(h) Prior Actions.—Nothing in this Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

SEC. ~~23~~ **24**. DEVELOPMENT AND EVALUATION OF TEST METHODS AND SUSTAINABLE CHEMISTRY.

Section 27 of the Toxic Substances Control Act (15 U.S.C. 2626) is amended—

(1) in subsection (a), in the first sentence by striking "Health, Education, and Welfare" and inserting "Health and Human Services"; and

(2) by adding at the end the following:

"(c) Sustainable Chemistry Program.—The President shall establish an interagency Sustainable Chemistry Program to promote and coordinate Federal sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities.

"(d) Program Activities.—The activities of the Program shall be designed to—

"(1) provide sustained support for sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training through—

"(A) coordination of sustainable chemistry research, development, demonstration, and technology transfer conducted at Federal laboratories and agencies; and

"(B) to the extent practicable, encouragement of consideration of sustainable chemistry in, as appropriate—

"(i) the conduct of Federal and State science and engineering research and development; and

"(ii) the solicitation and evaluation of applicable proposals for science and engineering research and development;

"(2) examine methods by which the Federal Government can create incentives for consideration and use of sustainable chemistry processes and products, including innovative financing mechanisms;

"(3) expand the education and training of undergraduate and graduate students and professional scientists and engineers, including through partnerships with industry, in sustainable chemistry science and engineering;

"(4) collect and disseminate information on sustainable chemistry research, development, and technology transfer including information on—

"(A) incentives and impediments to development, manufacturing, and commercialization;

"(B) accomplishments;

"(C) best practices; and

"(D) costs and benefits;

"(5) support (including through technical assistance, participation, financial support, or other forms of support) economic, legal, and other appropriate social science research to identify barriers to commercialization and methods to advance commercialization of sustainable chemistry.

"(e) Interagency Working Group.—

"(1) ESTABLISHMENT.—Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the President, in consultation with the Office of Science and Technology Policy, shall establish an Interagency Working Group that shall include representatives from the National Science Foundation, the National Institute of Standards and Technology, the Department of Energy, the Environmental Protection Agency, the Department of Agriculture, the Department of Defense, the National Institutes of Health, and any other agency that the President may designate to oversee the planning, management, and coordination of the Program.

"(2) GOVERNANCE.—The Director of the National Science Foundation and the Assistant Administrator for Research and Development of the Environmental Protection Agency, or their designees, shall serve as co-chairs of the Interagency Working Group.

"(3) RESPONSIBILITIES.—In overseeing the planning, management, and coordination of the Program, the Interagency Working Group shall—

"(A) establish goals and priorities for the Program, in consultation with the Advisory Council;

"(B) provide for interagency coordination, including budget coordination, of activities under the Program;

"(C) meet not later than 90 days from its establishment and periodically thereafter; and

"(D) establish and consult with an Advisory Council on a regular basis.

"(4) MEMBERSHIP.—The Advisory Council members shall not be employees of the Federal Government and shall include a diverse representation of knowledgeable individuals from the private sector (including small- and medium-sized enterprises from across the value chain), academia, State and tribal governments, and nongovernmental organizations and others who are in a position to provide expertise.

"(f) Agency Budget Requests.—

"(1) IN GENERAL.—Each Federal agency and department participating in the Program shall, as part of its annual request for appropriations to the Office of Management and Budget, submit a report to the Office of Management and Budget that—

"(A) identifies the activities of the agency or department that contribute directly to the Program; and

"(B) states the portion of the agency or department's request for appropriations that is allocated to those activities.

"(2) ANNUAL BUDGET REQUEST TO CONGRESS.—The President shall include in the annual budget request to Congress a statement of the portion of the annual budget request for each agency or department that will be allocated to activities undertaken pursuant to the Program.

"(g) Report to Congress.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Interagency Working Group shall submit a report to the Committee on Science, Space, and Technology and Committee on Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works and the Committee on Commerce, Science, and Transportation of the Senate that shall include—

"(A) a summary of federally funded sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities;

"(B) a summary of the financial resources allocated to sustainable chemistry initiatives;

"(C) an analysis of the progress made toward achieving the goals and priorities of the program established pursuant to subsection (c), and recommendations for future program activities;

"(D) an assessment of the benefits of expanding existing, federally-supported regional innovation and manufacturing hubs to include sustainable chemistry and the value of directing the creation of 1 or more dedicated sustainable chemistry centers of excellence or hubs; and

"(E) an evaluation of steps taken and future strategies to avoid duplication of efforts, streamline interagency coordination, facilitate information sharing, and spread best practices between participating agencies in the Program.

"(2) SUBMISSION TO GAO.—The Interagency Working Group shall also submit the report described in paragraph (1) to the Government Accountability Office for consideration in future Congressional inquiries.".

SEC. ~~24~~ **25**. STATE PROGRAMS.

Section 28 of the Toxic Substances Control Act (15 U.S.C. 2627) is amended—

(1) in subsection (b)(1)—

(A) in subparagraphs (A) through (D), by striking the comma at the end of each subparagraph and inserting a semicolon; and

(B) in subparagraph (E), by striking ", and" and inserting "; and"; and

(2) by striking subsections (c) and (d).

SEC. ~~25~~ **26**. AUTHORIZATION OF APPROPRIATIONS.

Section 29 of the Toxic Substances Control Act (15 U.S.C. 2628) is repealed.

SEC. ~~26~~ **27**. ANNUAL REPORT.

Section 30 of the Toxic Substances Control Act (15 U.S.C. 2629) is amended by striking paragraph (2) and inserting the following:

"(2)(A) the number of notices received during each year under section 5; and

"(B) the number of the notices described in subparagraph (A) for chemical substances subject to a rule, testing consent agreement, or order under section 4;".

SEC. ~~27~~ **28**. EFFECTIVE DATE.

Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601 note; Public Law 94–469) is amended—

(1) by striking "Except as provided in section 4(f), this" and inserting the following:

"(a) In General.—This"; and

(2) by adding at the end the following:

"(b) Retroactive Applicability.—Nothing in this Act shall be interpreted to apply retroactively to any State, Federal, or maritime legal action commenced prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

Purpose: In the nature of a substitute.

S. 697

To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE INTENDED TO BE PROPOSED BY _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act".

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(c) of the Toxic Substances Control Act (15 U.S.C. 2601(c)) is amended—

(1) by striking "It is the intent" and inserting the following:

"(1) ADMINISTRATION.—It is the intent";

(2) in paragraph (1) (as so redesignated), by inserting ", as provided under this Act" before the period at the end; and

(3) by adding at the end the following:

"(2) REFORM.—This Act, including reforms in accordance with the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act—

"(A) shall be administered in a manner that—

"(i) protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and

"(ii) ensures that appropriate information on chemical substances and mixtures is available to public health officials and first responders in the event of an

emergency; and

"(B) shall not displace or supplant common law rights of action or remedies for civil relief.".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) by redesignating paragraphs (4), (5), (6), (7), (8), (9), (10), (11), (12), (13), and (14) as paragraphs (5), (6), (7), (8), (9), (10), (12), (13), (17), (18), and (19), respectively;

(2) by inserting after paragraph (3) the following:

"(4) CONDITIONS OF USE.—The term 'conditions of use' means the intended, known, or reasonably foreseeable circumstances the Administrator determines a chemical substance is manufactured, processed, distributed in commerce, used, or disposed of.";

(3) by inserting after paragraph (10) (as so redesignated) the following:

"(11) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.—The term 'potentially exposed or susceptible population' means 1 or more groups—

"(A) of individuals within the general population who may be—

"(i) differentially exposed to chemical substances under the conditions of use; or

"(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

"(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; and

(4) by inserting after paragraph (13) (as so redesignated) the following:

"(14) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.

"(15) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the conditions of use.

"(16) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of injury to health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of injury to—

"(A) the general population; or

"(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

The Toxic Substances Control Act is amended by inserting after section 3 (15 U.S.C. 2602) the following:

"SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

"(a) Definition of Guidance.—In this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.

"(b) Deadline.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.

"(c) Use of Science.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance on the use of science in making decisions under sections 4, 4A, 5, and 6.

"(2) GOAL.—A goal of the policies, procedures, and guidance described in paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) REQUIREMENTS.—The policies, procedures, and guidance issued under this section shall ensure that—

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;

"(B) to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate existing relevant policies, procedures, and guidance, as appropriate and consistent with this Act.

"(e) Review.—Not later than 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(1) review the adequacy of any policies, procedures, and guidance developed under this section, including animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this Act; and

"(2) after providing public notice and an opportunity for comment, revise the policies, procedures, and guidance if necessary to reflect new scientific developments or understandings.

"(f) Sources of Information.—In carrying out sections 4, 4A, 5, and 6, the Administrator shall take into consideration information relating to a chemical substance, including hazard and exposure information, under the conditions of use that is reasonably available to the Administrator, including information that is—

"(1) submitted to the Administrator pursuant to any rule, consent agreement, order, or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act, by—

"(A) manufacturers or processors of a substance;

"(B) the public;

"(C) other Federal departments or agencies; or

"(D) the Governor of a State or a State agency with responsibility for protecting health or the environment;

"(2) submitted to a governmental entity in any jurisdiction pursuant to a governmental requirement relating to the protection of health or the environment; or

"(3) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible by the Administrator.

"(g) Testing of Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance for the testing of chemical substances or mixtures under section 4.

"(2) GOAL.—A goal of the policies, procedures, and guidance established under paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) CONTENTS.—The policies, procedures, and guidance established under paragraph (1) shall—

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential; and

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations.

"(4) EPIDEMIOLOGICAL STUDIES.—Before prescribing epidemiological studies of employees, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health.

"(h) Safety Assessments and Safety Determinations.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(C) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall identify the substances subject to safety assessments and safety determinations to be completed that year.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(A) IN GENERAL.—The Administrator shall establish, by rule, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

"(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

"(C) MINIMUM REQUIREMENTS.—The policies and procedures under this paragraph shall, at a minimum—

"(i) describe—

"(I) the manner in which the Administrator will identify informational needs and seek that information from the public;

"(II) the information (including draft safety assessments) that may be submitted by interested individuals or entities, including States; and

"(III) the criteria by which information submitted by interested individuals or entities will be evaluated;

"(ii) require that each draft and final safety assessment and safety determination of the Administrator include a description of—

"(I)(aa) the scope of the safety assessment and safety determination to be conducted under section 6, including the hazards, exposures, and conditions of use of the chemical substance, and potentially exposed and susceptible populations that the Administrator has considered in a safety assessment; and

"(bb) the basis for the scope of the safety assessment and safety

determination;

"(II) the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the conditions of use were considered, and the basis for that consideration;

"(III) the weight of the scientific evidence of risk; and

"(IV) the information regarding the impact on health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies;

"(iii) establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination; and

"(iv) when relevant information is provided or otherwise made available to the Administrator, require the Administrator to consider the extent of Federal regulation under other Federal laws.

"(D) GUIDANCE.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop guidance to assist interested persons in developing their own draft safety assessments and other information for submission to the Administrator, which may be considered ~~at the discretion of~~by the Administrator.

"(ii) REQUIREMENT.—The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing a draft safety assessment for consideration by the Administrator.

"(i) Publicly Available Information.—Subject to section 14, the Administrator shall—

"(1) make publicly available a nontechnical summary, and the final version, of each safety assessment and safety determination;

"(2) provide public notice and an opportunity for comment on each proposed safety assessment and safety determination; and

"(3) make public in a final safety assessment and safety determination—

"(A) the list of studies considered by the Administrator in carrying out the safety assessment or safety determination; and

"(B) the list of policies, procedures, and guidance that were followed in carrying out the safety assessment or safety determination.

"(j) Consultation With Science Advisory Committee on Chemicals.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish an advisory committee, to be known as the 'Science Advisory Committee on Chemicals' (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, on the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(5) RELATIONSHIP TO OTHER LAW.—All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).".

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking subsections (a), (b), (c), (d), (e), and (g);

(2) in subsection (f)—

(A) in the first sentence—

(i) by striking "from cancer, gene mutations, or birth defects"; and

(ii) by inserting ", without taking into account cost or other nonrisk factors" before the period at the end; and

(B) by striking the last sentence; and

(3) by inserting before subsection (f) the following:

"(a) Development of New Information on Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section if the Administrator determines that the information is necessary—

"(A) to review a notice under section 5(d) or to perform a safety assessment or safety determination under section 6;

"(B) to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4) or under a rule promulgated under section 6(d)(3);

"(C) pursuant to section 12(a)(4); or

"(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

"(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.

"(B) PROHIBITION.—Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.

"(C) LIMITATION.—The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

"(3) FORM.—The Administrator may require the development of information described in paragraph (1) or (2) by—

"(A) promulgating a rule;

"(B) entering into a testing consent agreement; or

"(C) issuing an order.

"(4) CONTENTS.—

"(A) IN GENERAL.—A rule, testing consent agreement, or order issued under this subsection shall include—

"(i) identification of the chemical substance or mixture for which testing is required;

"(ii) identification of the persons required to conduct the testing;

"(iii) test protocols and methodologies for the development of information for the chemical substance or mixture, including specific reference to any reliable nonanimal test procedures; and

"(iv) specification of the period within which individuals and entities required to conduct the testing shall submit to the Administrator the information developed in accordance with the procedures described in clause (iii).

"(B) CONSIDERATIONS.—In determining the procedures and period to be required under subparagraph (A), the Administrator shall take into consideration—

"(i) the relative costs of the various test protocols and methodologies that may be required; and

"(ii) the reasonably foreseeable availability of facilities and personnel required to perform the testing.

"(5) CONSIDERATION OF FEDERAL AGENCY RECOMMENDATIONS.—The Administrator shall consider the recommendations of other Federal agencies regarding the chemical substances and mixtures to which the Administrator shall give priority consideration under this section.

"(b) Statement of Need.—

"(1) IN GENERAL.—In promulgating a rule, entering into a testing consent agreement, or issuing an order for the development of additional information (including information on exposure or exposure potential) pursuant to this section, the Administrator shall—

"(A) identify the need intended to be met by the rule, agreement, or order;

"(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of vertebrate animals.

"(2) EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an order is warranted instead of promulgating a rule or entering into a testing consent agreement.

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a description of—

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

"(ii) the extent to which the Administrator has obtained or attempted to obtain the information through voluntary submissions; and

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) prior to making a request or adopting a requirement for testing using vertebrate animals, taking into consideration, as appropriate and to the extent practicable, reasonably available—

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

"(iii) high-throughput screening methods and the prediction models of those methods; and

"(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information;

"(B) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would

provide reliable and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

"(I) animal-based studies; and

"(II) emerging methods and models; and

"(C) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information under this title that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

"(C) identify in the strategic plan developed under subparagraph (A) particular alternative test methods or testing strategies that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information of equivalent scientific reliability and quality to that which would be obtained from vertebrate animal testing;

"(D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific reliability, relevance, and equivalent information and the test methods and strategies identified in subparagraph (C);

"(E) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation;

"(F) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing under this title; and

"(G) identify synergies with the related information requirements of other jurisdictions to minimize the potential for additional or duplicative testing.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(4) VOLUNTARY TESTING.—

"(A) IN GENERAL.—Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative or nonanimal test method or testing strategy that the Administrator has determined under paragraph (2)(C) to be scientifically reliable, relevant, and capable of providing equivalent information, before conducting new animal testing.

"(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph—

"(i) requires the Administrator to review the basis on which the person is conducting testing described in subparagraph (A);

"(ii) prohibits the use of other test methods or testing strategies by any person for purposes other than developing information for submission under this title on a voluntary basis; or

"(iii) prohibits the use of other test methods or testing strategies by any person, subsequent to the attempt to develop information using the test methods and testing strategies identified by the Administrator under paragraph (2)(C).

"(d) Testing Requirements.—

"(1) IN GENERAL.—The Administrator may require the development of information by—

"(A) manufacturers and processors of the chemical substance or mixture; and

"(B) persons that begin to manufacture or process the chemical substance or mixture after the effective date of the rule, testing consent agreement, or order.

"(2) DESIGNATION.—The Administrator may permit 2 or more persons identified in subparagraph (A) or (B) of paragraph (1) to designate 1 of the persons or a qualified third party—

"(A) to develop the information; and

"(B) to submit the information on behalf of the persons making the designation.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—A person otherwise subject to a rule, testing consent agreement, or order under this section may submit to the Administrator an application for an exemption on the basis that submission of information by the applicant on the chemical substance or mixture would be duplicative of—

"(i) information on the chemical substance or mixture that—

"(I) has been submitted to the Administrator pursuant to a rule, consent agreement, or order under this section; or

"(II) is being developed by a person designated under paragraph (2); or

"(ii) information on an equivalent chemical substance or mixture that—

"(I) has been submitted to the Administrator pursuant to a rule, consent agreement, or order under this section; or

"(II) is being developed by a person designated under paragraph (2).

"(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

"(i) IN GENERAL.—If the Administrator accepts an application submitted under subparagraph (A), before the end of the reimbursement period described in clause (iii), the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as agreed to between the applicant and the designee.

"(ii) ARBITRATION.—If the applicant and a person designated under paragraph (2) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.

"(iii) REIMBURSEMENT PERIOD.—For the purposes of this subparagraph, the reimbursement period for any information for a chemical substance or mixture is a period—

"(I) beginning on the date the information is submitted in accordance with a rule, testing consent agreement, or order under this section; and

"(II) ending on the later of—

"(aa) 5 years after the date referred to in subclause (I); or

"(bb) the last day of the period that begins on the date referred to in subclause (I) and that is equal to the period that the Administrator determines was necessary to develop the information.

"(C) TERMINATION.—If, after granting an exemption under this paragraph, the Administrator determines that no person designated under paragraph (2) has complied with the rule, testing consent agreement, or order, the Administrator shall—

"(i) by order, terminate the exemption; and

"(ii) notify in writing each person that received an exemption of the requirements with respect to which the exemption was granted.

"(4) TIERED TESTING.—

"(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.

"(B) SCREENING-LEVEL TESTS.—

"(i) IN GENERAL.—The screening-level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.

"(ii) USE.—Screening-level tests shall be used—

"(I) to screen chemical substances or mixtures for potential adverse effects; and

"(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.

"(C) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for safety assessments or safety determinations, the Administrator may require more advanced tests for potential health or environmental effects or exposure potential.

"(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

"(e) Transparency.—Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders and all information submitted under this section.".

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the third sentence by inserting "(as in effect on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act)" after "Toxic Substances Control Act".

SEC. 6. PRIORITIZATION SCREENING.

The Toxic Substances Control Act is amended by inserting after section 4 (15 U.S.C. 2603) the following:

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) Prioritization Screening Process and List of Substances.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish, by rule, a risk-based screening process and criteria for

identifying existing chemical substances that are—

"(A) a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances'); and

"(B) a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').

"(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(A) IN GENERAL.—Before the date of promulgation of the rule under paragraph (1) and not later than 180 days after the date of enactment of this section, the Administrator shall publish an initial list of high-priority substances and low-priority substances.

"(B) REQUIREMENTS.—

"(i) IN GENERAL.—The initial list of chemical substances shall contain at least 10 high-priority substances, at least 5 of which are drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, and at least 10 low-priority substances.

"(ii) SUBSEQUENTLY IDENTIFIED SUBSTANCES.—Insofar as possible, at least 50 percent of all substances subsequently identified by the Administrator as high-priority substances shall be drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, until all Work Plan chemicals have been designated under this subsection.

"(iii) PERSISTENCE AND BIOACCUMULATION.—In developing the initial list and in identifying additional high-priority substances, the Administrator shall give preference to chemical substances scored as high for persistence and bioaccumulation in the October 2014 TSCA Work Plan and subsequent updates.

"(C) ADDITIONAL CHEMICAL REVIEWS.—The Administrator shall, as soon as practicable and not later than—

"(i) 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 20 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 20 low-priority substances have been designated; and

"(ii) 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 25 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 25 low-priority substances have been designated.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In implementing the prioritization screening process established under paragraph (1), the Administrator shall take into consideration active substances, as determined under section 8, which may include chemical substances on the interim list of active substances established under that section.

"(ii) INACTIVE SUBSTANCES.—In implementing the prioritization screening process established under paragraph (1), the Administrator may take into consideration inactive substances, as determined under section 8, that the Administrator determines—

"(I)(aa) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) have the potential for high hazard and widespread exposure; or

"(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) with respect to which there exists the potential for residual high hazards or widespread exposures not otherwise addressed by the regulatory or other action.

"(iii) REPOPULATION.—

"(I) IN GENERAL.—On the completion of a safety determination under section 6 for a chemical substance, the Administrator shall remove the chemical substance from the list of high-priority substances established under this subsection.

"(II) ADDITIONS.—The Administrator shall add at least 1 chemical substance to the list of high-priority substances for each chemical substance removed from the list of high-priority substances established under this subsection, until a safety assessment and safety determination is completed for all chemical substances not designated as high-priority.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) except as provided under paragraph (2), not later than 180 days after the effective date of the final rule under paragraph (1), begin the prioritization screening process; and

"(II) make every effort to complete the designation of all active substances as high-priority substances or low-priority substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical substance as a high-priority substance or low-priority substance.

"(iii) CONSIDERATION.—

"(I) IN GENERAL.—The Administrator shall screen substances and designate high-priority substances taking into consideration the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in a timely manner.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.

"(C) SCREENING OF CATEGORIES OF SUBSTANCES.—The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate designations of high-priority substances and low-priority substances and safety assessments and safety determinations for high-priority substances.

"(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—The Administrator shall keep current and publish a list of chemical substances that includes and identifies substances—

"(i) that are being considered in the prioritization screening process and the status of the substances in the prioritization process;

"(ii) for which prioritization decisions have been postponed pursuant to subsection (b)(5), including the basis for the postponement; and

"(iii) that are designated as high-priority substances or low-priority substances, including the bases for such designations.

"(4) CRITERIA.—The criteria described in paragraph (1) shall account for—

"(A) the recommendation of the Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances appropriate for prioritization screening;

"(B) the hazard and exposure potential of the chemical substance (or category of substances), including persistence, bioaccumulation, and specific scientific classifications and designations by authoritative governmental entities;

"(C) the conditions of use or significant changes in the conditions of use of the chemical substance;

"(D) evidence and indicators of exposure potential to humans or the environment from the chemical substance, including potentially exposed or susceptible populations;

"(E) the volume of a chemical substance manufactured or processed;

"(F) whether the volume of a chemical substance as reported pursuant to a rule promulgated pursuant to section 8(a) has significantly increased or decreased;

"(G) the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

"(H) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a high-priority or a low-priority substance.

"(b) Prioritization Screening Process and Decisions.—

"(1) IN GENERAL.—In implementing the prioritization screening process developed under subsection (a), the Administrator shall—

"(A) identify the chemical substances being considered for prioritization;

"(B) request interested persons to supply information regarding the chemical substances being considered;

"(C) apply the criteria identified in subsection (a)(4); and

"(D) subject to paragraph (5) and using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.

"(2) REASONABLY AVAILABLE INFORMATION.—The prioritization screening decision regarding a chemical substance shall consider any hazard and exposure information relating to the chemical substance that is reasonably available to the Administrator.

"(3) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(A) shall identify as a high-priority substance a chemical substance that, relative to other active chemical substances, the Administrator determines has the potential for significant hazard and significant exposure;

"(B) may identify as a high-priority substance a chemical substance that, relative to other active chemical substances, the Administrator determines has the potential for significant hazard or significant exposure; and

"(C) may identify as a high-priority substance an inactive substance, as determined under subsection (a)(3)(A)(ii) and section 8(b), that the Administrator determines warrants a safety assessment and safety determination under section 6.

"(4) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that the chemical substance is likely to meet the safety standard.

"(5) POSTPONING A DECISION.—If the Administrator determines that additional information is needed to establish the priority of a chemical substance under this section, the Administrator may postpone a prioritization screening decision for a reasonable period—

"(A) to allow for the submission of additional information by an interested person and for the Administrator to evaluate the additional information; or

"(B) to require the development of information pursuant to a rule, testing consent agreement, or order issued under section 4(a)(2).

"(6) DEADLINES FOR SUBMISSION OF INFORMATION.—If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of the information.

"(7) NOTICE AND COMMENT.—The Administrator shall—

"(A) publish, including in the Federal Register, the proposed decisions made under paragraphs (3), (4), and (5) and the basis for the decisions;

"(B) identify the information and analysis on which the ~~documents~~ decisions are based; and

"(C) provide 90 days for public comment.

"(8) REVISIONS OF PRIOR DESIGNATIONS.—

"(A) IN GENERAL.—At any time, ~~and at the discretion of the Administrator,~~ the Administrator may revise the designation of a chemical substance as a high-priority substance or a low-priority substance based on information available to the Administrator after the date of the determination under paragraph (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.

"(9) OTHER INFORMATION RELEVANT TO PRIORITIZATION.—

"(A) IN GENERAL.—If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State proposes an administrative action or enacts a statute or takes an administrative action to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not designated as a high-priority substance, the Governor or State agency with responsibility for implementing the statute or administrative action shall notify the Administrator.

"(B) REQUESTS FOR INFORMATION.—Following receipt of a notification provided under subparagraph (A), the Administrator may request any available information from the Governor or the State agency with respect to—

"(i) scientific evidence related to the hazards, exposures and risks of the chemical substance under the conditions of use which the statute or administrative action is intended to address;

"(ii) any State or local conditions which warranted the statute or administrative action;

"(iii) the statutory or administrative authority on which the action is based; and

"(iv) any other available information relevant to the prohibition or other restriction, including information on any alternatives considered and their hazards, exposures, and risks.

"(C) PRIORITIZATION SCREENING.—The Administrator shall conduct a prioritization screening under this subsection for all substances that—

"(i) are the subject of notifications received under subparagraph (A); and

"(ii) the Administrator determines—

"(I) are likely to have significant health or environmental impacts;

"(II) are likely to have significant impact on interstate commerce; or

"(III) have been subject to a prohibition or other restriction under a statute or administrative action in 2 or more States.

"(D) AVAILABILITY TO PUBLIC.—Subject to section 14 and any applicable State law regarding the protection of confidential information provided to the State or to the Administrator, the Administrator shall make information received from a Governor or State agency under subparagraph (A) publicly available.

"(E) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall preempt a State statute or administrative action, require approval of a State statute or administrative action, or apply section 15 to a State.

"(10) REVIEW.—Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Administrator shall—

"(A) review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and

"(B) if necessary, modify the prioritization screening process.

"(11) EFFECT.—Subject to section 18, a designation by the Administrator under this section with respect to a chemical substance shall not affect—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance; or

"(B) the regulation of those activities.

"(c) Additional Priorities for Safety Assessments and Determinations.—

"(1) REQUIREMENTS.—

"(A) IN GENERAL.—The rule promulgated under subsection (a) shall—

"(i) include a process by which a manufacturer or processor of an active chemical substance that has not been designated a high-priority substance or is not in the process of a prioritization screening by the Administrator, may request that the Administrator designate the substance as an additional priority for a safety assessment and safety determination, subject to the payment of fees pursuant to section 26(b)(3)(D);

"(ii) specify the information to be provided in such requests; and

"(iii) specify the criteria (which may include criteria identified in subsection (a)(4)) that the Administrator shall use to determine whether or not to grant such a request, which shall include whether the substance is subject to restrictions imposed by statutes enacted or administrative actions taken by 1 or more States on the manufacture, processing, distribution in commerce, or use of the substance.

"(B) PREFERENCE.—Subject to paragraph (2), in deciding whether to grant requests under this subsection the Administrator shall give a preference to requests concerning substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

"(C) EXCEPTIONS.—Chemical substances for which requests have been granted under this subsection shall not be subject to subsection (a)(3)(A)(iii) or section 18(b).

"(2) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

"(A) the number of substances designated to undergo safety assessments and safety determinations under the process and criteria pursuant to paragraph (1) is not less than 25 percent, or more than 30 percent, of the cumulative number of substances designated to undergo safety assessments and safety determinations under subsections (a)(2) and (b)(3) (except that if less than 25 percent are received by the Administrator, the Administrator shall grant each request that meets the requirements of paragraph (1));

"(B) the resources allocated to conducting safety assessments and safety determinations for additional priorities designated under this subsection are proportionate to the number of such substances relative to the total number of substances currently designated to undergo safety assessments and safety determinations under this section; and

"(C) the number of additional priority requests stipulated under subparagraph (A) is in addition to the total number of high-priority substances identified under subsections (a)(2) and (b)(3).

"(3) ADDITIONAL REVIEW OF WORK PLAN CHEMICALS FOR SAFETY ASSESSMENT AND SAFETY DETERMINATION.—In the case of a request under paragraph (1) with respect to a chemical substance identified by the Administrator in the October 2014 Work Plan—

"(A) the 30-percent cap specified in paragraph (2)(A) shall not apply and the addition of Work Plan chemicals shall be at the discretion of the Administrator; and

"(B) notwithstanding paragraph (1)(C), requests for additional Work Plan chemicals under this subsection shall be considered high-priority chemicals subject to section 18(b) but not subsection (a)(3)(A)(iii).

"(4) REQUIREMENTS.—

"(A) IN GENERAL.—The public shall be provided notice and an opportunity to comment on requests submitted under this subsection.

"(B) DECISION BY ADMINISTRATOR.—Not later than 180 days after the date on which the Administrator receives a request under this subsection, the Administrator shall decide whether or not to grant the request.

"(C) ASSESSMENT AND DETERMINATION.—If the Administrator grants a request under this subsection, the safety assessment and safety determination—

"(i) shall be conducted in accordance with the deadlines and other requirements

of sections 3A(i) and 6; and

"(ii) shall not be expedited or otherwise subject to special treatment relative to high-priority substances designated pursuant to subsection (b)(3) that are undergoing safety assessments and safety determinations.".

SEC. 7. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.";

(2) by striking subsection (b);

(3) by redesignating subsection (a) as subsection (b);

(4) by redesignating subsection (i) as subsection (a) and moving the subsection so as to appear at the beginning of the section;

(5) in subsection (b) (as so redesignated)—

(A) in the subsection heading, by striking "In General" and inserting "Notices";

(B) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking "subsection (h)" and inserting "paragraph (3) and subsection (h)"; and

(ii) in the matter following subparagraph (B)—

(I) by striking "subsection (d)" and inserting "subsection (c)"; and

(II) by striking "and such person complies with any applicable requirement of subsection (b)"; and

(C) by adding at the end the following:

"(3) ARTICLE CONSIDERATION.—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification.";

(6) by redesignating subsections (c) and (d) as subsections (d) and (c), respectively, and moving subsection (c) (as so redesigned) so as appear after subsection (b) (as redesignated by paragraph (3));

(7) in subsection (c) (as so redesignated)—

(A) by striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—The notice required by subsection (b) shall include, with respect to a chemical substance—

"(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

"(B) all known or reasonably ascertainable information regarding conditions of use and reasonably anticipated exposures.";

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A)—

(I) by striking "subsection (a)" and inserting "subsection (b)"; and

(II) by striking "or of data under subsection (b)";

(ii) in subparagraph (A), by adding "and" after the semicolon at the end;

(iii) in subparagraph (B), by striking "; and" and inserting a period; and

(iv) by striking subparagraph (C); and

(C) in paragraph (3), by striking "subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "subsection (b) and for which the notification period prescribed by subsection (b) or (d)";

(8) by striking subsection (d) (as redesignated by paragraph (6)) and inserting the following:

"(d) Review of Notice.—

"(1) INITIAL REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall—

"(i) conduct an initial review of the notice;

"(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

"(iii) make a determination under paragraph (3).

"(B) EXTENSION.—Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.

"(2) INFORMATION SOURCES.—In evaluating a notice under paragraph (1), the Administrator shall take into consideration—

"(A) any relevant information identified in subsection (c)(1); and

"(B) any other relevant additional information available to the Administrator.

"(3) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), based on the information described in paragraph (2), and subject to section 18(g), the Administrator shall determine that—

"(A) the relevant chemical substance or significant new use is not likely to meet the safety standard, in which case the Administrator shall take appropriate action under paragraph (4);

"(B) the relevant chemical substance or significant new use is likely to meet the safety standard, in which case the Administrator shall allow the review period to expire without additional restrictions; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraphs (4) and (5).

"(4) RESTRICTIONS.—

"(A) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—If the Administrator makes a determination under subparagraph (A) or (C) of paragraph (3) with respect to a notice submitted under subsection (b)—

"(I) the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, as appropriate, shall prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the restrictions specified in the consent agreement or order that the Administrator determines are sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard; and

"(II) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, except in compliance with the restrictions specified in the consent agreement or order.

"(ii) LIKELY TO MEET STANDARD.—If the Administrator makes a determination under subparagraph (B) of paragraph (3) with respect to a chemical substance or significant new use for which a notice was submitted under subsection (b), at the end of the applicable period for review under paragraph (1), the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use.

"(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall—

"(i) consider whether to promulgate a rule pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the consent agreement or order; and

"(ii)(I) initiate a rulemaking described in clause (i); or

"(II) publish a statement describing the reasons of the Administrator for not

initiating a rulemaking.

"(C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include, as appropriate—

"(i) subject to section 18(g), a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator

"(ii) a requirement that manufacturers or processors of the chemical substance shall—

"(I) make and retain records of the processes used to manufacture or process, as applicable, the chemical substance; or

"(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, use, or disposal, as applicable, of the chemical substance, subject to section 4;

"(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

"(I) in general; or

"(II) for a particular use;

"(iv) a prohibition or other restriction of—

"(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

"(II) any method of commercial use of the chemical substance; or

"(III) any method of disposal of the chemical substance; or

"(v) a prohibition or other restriction on the manufacture, processing, or distribution in commerce of the chemical substance—

"(I) in general; or

"(II) for a particular use.

"(D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines that, with respect to ~~ranks high for~~ persistence and bioaccumulation, scores high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February, 2012, the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance is likely to meet the safety standard, reduce potential exposure to the substance to the maximum extent practicable.

"(E) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior

to adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(F) DEFINITION OF REQUIREMENT.—For purposes of this Act, the term 'requirement' as used in this section does not displace common law.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

"(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(C) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

"(D) on receipt of information the Administrator finds supports the determination under paragraph (3), shall promptly make the determination.";

(9) by striking subsections (e) through (g) and inserting the following:

"(e) Notice of Commencement.—

"(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—

"(A) the name of the manufacturer; and

"(B) the initial date of nonexempt commercial manufacture.

"(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

"(f) Further Evaluation.—The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—

"(1) a notice of commencement for a chemical substance under subsection (e); or

"(2) new information regarding the chemical substance.

"(g) Transparency.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, consent agreements, rules, and orders submitted under this section or made by the Administrator under this section; and

"(2) all information submitted or issued under this section."; and

(10) in subsection (h)—

(A) in paragraph (1)—